

US3552444 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:34:33

All time stamps listed in this document are displayed in GMT

US3552444

Form: Participant Creation

Generated On: 26 Nov 2020 09:34:33

[Participant ID](#)

US3552444

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

US3552444

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
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 09:34:33

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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 09:34:33

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:34:33

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1954
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 1954
Start Year (derived)	1954
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

Condition	LEFT SHOULDER PAIN
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1954
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 1954
Start Year (derived)	1954
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

Condition	HYPERTENSION
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 09:34:33

Condition	GASTROESOPHAGEAL REFLUX DISEASE
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 (6)

Generated On: 26 Nov 2020 09:34:33

Condition	L4 L5 BACK PAIN
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 (7)

Generated On: 26 Nov 2020 09:34:33

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

Condition	SKIN CANCER
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

Condition	CHRONIC SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1954
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 1954
Start Year (derived)	1954
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

Condition	AORTIC STENOSIS
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 (14)

Generated On: 26 Nov 2020 09:34:33

Condition	HYPERCHOLESTEROLEMIA
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 (15)

Generated On: 26 Nov 2020 09:34:33

Condition	DENTAL DECAY
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)	13 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	16 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:41 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:41
Height (<i>xxx.x</i>)	74 in
Weight (<i>xxx.x</i>)	212 lb
BMI (<i>xxx.x</i>)	27.27610 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 09:34:33

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.

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

GYM ONCE A WEEK, GROCERY ONCE A WEEK, GOLF ONCE A WEEK, SOCIALIZE AT FRIENDS HOUSE ONCE A WEEK (MASKS, 6FT APART), WALKS IN PARKS, CLEANING AND MAINTENANCE WORKERS COME INTO THE HOUSE

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

What was the date of randomization? (dd MMM yyyy) 16 SEP 2020

What was the participant's randomization number? 190971

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 09:34:33

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 09:34:33

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)	16 SEP 2020
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:41
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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)	16 SEP 2020
Time of assessment (00:00-23:59)	14:49 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:49
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

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 09:34:33

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)	14:19 (24 HR)
Treatment Date and Time (derived)	16 SEP 2020 14:19
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 09:34:33

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:50 (24 HR)
Collection date and time (derived)	16 SEP 2020 13:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:33

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	13:55	16 SEP 2020 13:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

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 09:34:33

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp 16 SEP 2020 14:53

PC Open Date & Time 16 SEP 2020 14:39

PC Close Date & Time 16 SEP 2020 17:09

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:09

PC Open Date & Time

16 SEP 2020 18:04

PC Close Date & Time

17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 14:06

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:33

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:27

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:33

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

96.8 °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

19 SEP 2020 13:26

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:33

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

97.2 °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

20 SEP 2020 16:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

21 SEP 2020 15:41

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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 12:13

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

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 14:55

PC Open Date & Time

16 SEP 2020 14:39

PC Close Date & Time

16 SEP 2020 17:09

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

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 18:09

PC Open Date & Time

16 SEP 2020 18:04

PC Close Date & Time

17 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

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

17 SEP 2020 14:06

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

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

18 SEP 2020 12:28

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

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

19 SEP 2020 13:26

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

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

20 SEP 2020 16:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

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

21 SEP 2020 15:41

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

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

22 SEP 2020 12:13

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 14:55
PC Open Date & Time	16 SEP 2020 14:39
PC Close Date & Time	16 SEP 2020 17:09

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 18:10
PC Open Date & Time	16 SEP 2020 18:04
PC Close Date & Time	17 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

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 ☒

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

Yes ☐	
PC Time stamp	17 SEP 2020 14:06
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

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 ☒

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

Yes ☐	
PC Time stamp	18 SEP 2020 12:28
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

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 ☒

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

Yes ☐	
PC Time stamp	19 SEP 2020 13:26
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

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 ☒

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

Yes ☐	
PC Time stamp	20 SEP 2020 16:08
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

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 ☒

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

Yes ☐	
PC Time stamp	21 SEP 2020 15:42
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

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 ☒

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

Yes ☐	
PC Time stamp	22 SEP 2020 12:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3552444

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552444

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 11:36
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

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.

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

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 WORSENING OF ARRHYTHMIA

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3552444

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	14 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:54 (24 HR)
Collection date and time (derived)	14 OCT 2020 11:54

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:33

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:59	14 OCT 2020 11:59
Nasopharyngeal Swab 2	No		

US3552444

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552444

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552444

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552444

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

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.

US3552444

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 NOV 2020
Collection time (<i>00:00-23:59</i>)	09:38 (24 HR)
Collection date and time (derived)	11 NOV 2020 09:38

US3552444

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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	17 NOV 2020 17:26:42
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 14:21:51
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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20 JUL 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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03 AUG 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

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06 AUG 2021 00:01

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10 AUG 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

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13 AUG 2021 00:01

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17 AUG 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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24 AUG 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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27 AUG 2021 00:01

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31 AUG 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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07 SEP 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

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10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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28 SEP 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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05 OCT 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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01 FEB 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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08 FEB 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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01 MAR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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15 MAR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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05 APR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

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08 APR 2022 00:01

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12 APR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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19 APR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

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06 MAY 2022 00:01

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10 MAY 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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21 JUN 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

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19 JUL 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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°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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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09 AUG 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

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23 AUG 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

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06 SEP 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

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13 SEP 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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20 SEP 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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27 SEP 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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04 OCT 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

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11 OCT 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3552444

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:34:33

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 ☐

US3552444

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:34:33

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552444

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:34:33

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

AEID	
Adverse event	EPISTAXIS
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)	11 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	309 of 1667

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

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)	

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

AEID	
Adverse event	WORSENING ATRIAL FIBRILLATION ARRHYTHMIA
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)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

311 of 1667

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:34:33

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

Yes ☒

No ☐

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	CLARITIN
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
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 ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

	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 2000
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	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

	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	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	DOXAZOSIN
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERTROPHY
Dose per administration	8
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 ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
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	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	ATENOLOL
Prophylaxis	Yes ☐ No ☒
Indication	ATRIAL FIBRILLATION
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	11 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	FINASTERIDE
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERTROPHY
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☒ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	NEXIUM
Prophylaxis	Yes ☐ No ☒
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
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	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	TADALAFIL
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERTROPHY
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	MELATONIN
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
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 ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

	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	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	ELIQUIS
Prophylaxis	Yes ☒ No ☐
Indication	COAGULATION PREVENTION
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

	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)		13 OCT 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	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	TOOTH EXTRACTION
Dose per administration	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 ☐ Intramuscular ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

	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)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 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 ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

Name of Medication	ATENOLOL
Prophylaxis	Yes ☐ No ☒
Indication	ATRIAL FIBRILLATION
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

	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)		12 OCT 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	☒

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

	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)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 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	☐

US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:34:33

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:34:33

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
13 OCT 2020	TOOTH EXTRACTION	Medical History	

US3552444

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:33

Date of dosing discontinuation (dd MMM yyyy)

14 OCT 2020

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

AE #3

US3552444

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:34:33

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 ☐

Audit

US3552444 (Prod: Saint Louis University)

US3552444

Form: Participant Creation

Generated On: 26 Nov 2020 09:34:33

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552444'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 18:44:32

US3552444

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:18:17

US3552444

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Sep 2020 18:44:33

US3552444

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:18:17

US3552444

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	17 Sep 2020 13:18:17

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered (b) (6) 1946'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Sep 2020 18:44:35

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Age](#)

Audit	User	Time (GMT)
User entered '74'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '74'	System	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Dublin (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

White

Audit	User	Time (GMT)
User entered '1'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

Unknown

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:33

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Sep 2020 18:44:33

US3552444

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:34:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:06

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:28:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:28:40
Data point term sent to Coder	System	17 Sep 2020 13:27:48
User entered 'seasonal allergies'	Stanley Doublin (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 1954'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 1954'	System	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '1954'	System	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 13:28:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 13:28:58
Data point term sent to Coder	System	17 Sep 2020 13:27:48
User entered 'left shoulder pain'	Stanley Doublin (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un Jun 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un Aug 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2020'	System	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2020'	System	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

[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)	17 Sep 2020 13:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:28:41
Data point term sent to Coder	System	17 Sep 2020 13:27:48
User entered 'asthma'	Stanley Doublin (b) (4)	17 Sep 2020 13:27:36
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 1954'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 1954'	System	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '1954'	System	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:28:41
Data point term sent to Coder	System	17 Sep 2020 13:27:48
User entered 'hypertension'	Stanley Doublin (b) (4)	17 Sep 2020 13:27:47
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2015'	System	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:29:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:29:39
Data point term sent to Coder	System	17 Sep 2020 13:28:49
User entered 'gastroesophageal reflux disease'	Stanley Doublin (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '1990'	System	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:46:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:46:42
Data point term sent to Coder	System	17 Sep 2020 13:29:50
User entered 'l4 l5 back pain'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '1990'	System	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Right inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:31:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:31:46
Data point term sent to Coder	System	17 Sep 2020 13:30:50
User entered 'right inguinal hernia'	Stanley Dublin (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:33:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:33:36
Data point term sent to Coder	System	17 Sep 2020 13:31:51
User entered 'left total knee replacement'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2010'	System	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2010'	System	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 13:33:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 13:33:36
Data point term sent to Coder	System	17 Sep 2020 13:31:51
User entered 'atrial fibrillation'	Stanley Dublin (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2019'	System	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:33:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:33:36
Data point term sent to Coder	System	17 Sep 2020 13:31:51
User entered 'benign prostatic hypertrophy'	Stanley Doublin (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2000'	System	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Skin cancer, LLT: Skin cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:33:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:33:37
Data point term sent to Coder	System	17 Sep 2020 13:32:52
User entered 'skin cancer'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2019'	System	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2019'	System	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:33:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:33:37
Data point term sent to Coder	System	17 Sep 2020 13:32:53
User entered 'chronic sinusitis'	Stanley Dublin (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 1954'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 1954'	System	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '1954'	System	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:34:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:34:39
Data point term sent to Coder	System	17 Sep 2020 13:33:54
User entered 'aortic stenosis'	Stanley Dublin (b) (4)	17 Sep 2020 13:33:30
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2015'	System	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

[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)	17 Sep 2020 13:34:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 13:34:40
Data point term sent to Coder	System	17 Sep 2020 13:33:54
User entered 'hypercholesterolemia'	Stanley Doublin (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2010'	System	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Dental decay - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 04:08:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 04:08:22
Data point term sent to Coder	System	02 Nov 2020 17:26:25
User entered 'Dental decay'	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:57
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:57
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:57
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	02 Nov 2020 17:26:39
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	02 Nov 2020 17:26:39
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	02 Nov 2020 17:26:13
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '13 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	02 Nov 2020 17:26:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:57
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	02 Nov 2020 17:26:13
User entered empty.	System	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Nov 2020 17:26:13
User entered empty.	System	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 15:52:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 15:52:21
Data point term sent to Coder	System	03 Nov 2020 15:51:32
User entered 'insomnia'	Cassandra Zehenny (b) (4)	03 Nov 2020 15:51:15
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Cassandra Zehenny (b) (4)	03 Nov 2020 15:51:15
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cassandra Zehenny (b) (4)	03 Nov 2020 15:51:15
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	03 Nov 2020 15:51:15
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	03 Nov 2020 15:51:15
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cassandra Zehenny (b) (4)	03 Nov 2020 15:51:15
	(b) (4)	

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '2019'	System	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '12:41'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:41'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '74' in	Stanley Dublin (b) (4)	17 Sep 2020 13:37:35
DataPoint set to visible.	(b) (4) System	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '212' lb	Stanley Dublin (b) (4)	17 Sep 2020 13:37:35
DataPoint set to visible.	(b) (4) System	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '27.27610'	System	17 Sep 2020 13:37:35
DataPoint set to visible.	System	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	17 Sep 2020 13:37:35
DataPoint set to visible.	System	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:45

US3552444

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:45

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

[Specify](#)

Audit	User	Time (GMT)
User entered 'gym once a week, grocery once a week, Stanley Dublin (b) (4) golf once a week, socialize at friends house once a (b) (4) week (masks, 6ft apart), walks in parks, cleaning and maintenance workers come into the house'		17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

Other

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:33

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:54

US3552444

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:54

US3552444

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:54

US3552444

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	17 Sep 2020 13:39:54

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 18:59:21

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '190971'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 18:59:21

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 18:59:21

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

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)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:40:09

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:40:09

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:40:09

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:40:09

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:40:09

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:33

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:22:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:22:18

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:33

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:33

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:33

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:33

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Dublin (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '12:41'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:41'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '14'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '135'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '89'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:33

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:33

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '14:49'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:49'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '50'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '12'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '109'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '75'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:48

US3552444

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:41:48

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

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 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:19'	(b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:19'	System	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:14

US3552444

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:14

US3552444

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:50'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:14

US3552444

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:50'	System	17 Sep 2020 13:42:14

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '13:55'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:55'	System	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:29:48

US3552444

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:29:48

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:53:25', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'fb86e89f-9235-4382-a734-3098f015b5f8'	System	16 Sep 2020 19:53:58
User entered 'Yes (Y)'	System	16 Sep 2020 19:53:58

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:53:34', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'fb86e89f-9235-4382-a734-3098f015b5f8'	System	16 Sep 2020 19:53:58
User entered '98.6'	System	16 Sep 2020 19:53:58

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:53:40', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'fb86e89f-9235-4382-a734-3098f015b5f8'	System	16 Sep 2020 19:53:58
User entered 'No (N)'	System	16 Sep 2020 19:53:58

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:53:54', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'fb86e89f-9235-4382-a734-3098f015b5f8'	System	16 Sep 2020 19:53:58
User entered '16 Sep 2020 14:53'	System	16 Sep 2020 19:53:58

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:39'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 17:09'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:08:14', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '08fd88fb-2469-47d3-b915-a2dbff28a131'	System	16 Sep 2020 23:09:16
User entered 'Yes (Y)'	System	16 Sep 2020 23:09:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:08:21', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '08fd88fb-2469-47d3-b915-a2dbff28a131'	System	16 Sep 2020 23:09:16
User entered '97.1'	System	16 Sep 2020 23:09:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:08:26', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '08fd88fb-2469-47d3-b915-a2dbff28a131'	System	16 Sep 2020 23:09:16
User entered 'No (N)'	System	16 Sep 2020 23:09:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:09:14', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '08fd88fb-2469-47d3-b915-a2dbff28a131'	System	16 Sep 2020 23:09:16
User entered '16 Sep 2020 18:09'	System	16 Sep 2020 23:09:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 18:04'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 2'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:05:46', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'af54d91f-8dcf-4065-b8f8-cde33a36d4b1'	System	17 Sep 2020 19:06:09
User entered 'Yes (Y)'	System	17 Sep 2020 19:06:09

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:05:54', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'af54d91f-8dcf-4065-b8f8-cde33a36d4b1'	System	17 Sep 2020 19:06:09
User entered '98.3'	System	17 Sep 2020 19:06:09

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:05:58', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'af54d91f-8dcf-4065-b8f8-cde33a36d4b1'	System	17 Sep 2020 19:06:09
User entered 'No (N)'	System	17 Sep 2020 19:06:09

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:06', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'af54d91f-8dcf-4065-b8f8-cde33a36d4b1'	System	17 Sep 2020 19:06:09
User entered '17 Sep 2020 14:06'	System	17 Sep 2020 19:06:09

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 3'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:27:12', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '3aa02a8d-f607-421b-88c4-aab4bdf74faa'	System	18 Sep 2020 17:27:40
User entered 'Yes (Y)'	System	18 Sep 2020 17:27:40

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:27:29', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '3aa02a8d-f607-421b-88c4-aab4bdf74faa'	System	18 Sep 2020 17:27:40
User entered '97.6'	System	18 Sep 2020 17:27:40

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:27:33', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '3aa02a8d-f607-421b-88c4-aab4bdf74faa'	System	18 Sep 2020 17:27:40
User entered 'No (N)'	System	18 Sep 2020 17:27:40

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:27:39', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '3aa02a8d-f607-421b-88c4-aab4bdf74faa'	System	18 Sep 2020 17:27:40
User entered '18 Sep 2020 12:27'	System	18 Sep 2020 17:27:40

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 4'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:25:42', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '452c83e9-daa9-4be9-8376-b2c39a492a04'	System	19 Sep 2020 18:26:13
User entered 'Yes (Y)'	System	19 Sep 2020 18:26:13

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:25:52', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '452c83e9-daa9-4be9-8376-b2c39a492a04'	System	19 Sep 2020 18:26:13
User entered '96.8'	System	19 Sep 2020 18:26:13

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:25:59', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '452c83e9-daa9-4be9-8376-b2c39a492a04'	System	19 Sep 2020 18:26:13
User entered 'No (N)'	System	19 Sep 2020 18:26:13

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:11', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '452c83e9-daa9-4be9-8376-b2c39a492a04'	System	19 Sep 2020 18:26:13
User entered '19 Sep 2020 13:26'	System	19 Sep 2020 18:26:13

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 5'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:07:59', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ca36ad64-6f94-4bb3-b236-a77b1af26345'	System	20 Sep 2020 21:08:16
User entered 'Yes (Y)'	System	20 Sep 2020 21:08:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:06', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ca36ad64-6f94-4bb3-b236-a77b1af26345'	System	20 Sep 2020 21:08:16
User entered '97.2'	System	20 Sep 2020 21:08:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:09', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ca36ad64-6f94-4bb3-b236-a77b1af26345'	System	20 Sep 2020 21:08:16
User entered 'No (N)'	System	20 Sep 2020 21:08:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:14', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ca36ad64-6f94-4bb3-b236-a77b1af26345'	System	20 Sep 2020 21:08:16
User entered '20 Sep 2020 16:08'	System	20 Sep 2020 21:08:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 6'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:13', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '31e5d93f-58bf-448a-a6e8-8b7e34b3ed95'	System	21 Sep 2020 20:41:33
User entered 'Yes (Y)'	System	21 Sep 2020 20:41:33

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:22', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '31e5d93f-58bf-448a-a6e8-8b7e34b3ed95'	System	21 Sep 2020 20:41:33
User entered '97.8'	System	21 Sep 2020 20:41:33

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:25', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '31e5d93f-58bf-448a-a6e8-8b7e34b3ed95'	System	21 Sep 2020 20:41:33
User entered 'No (N)'	System	21 Sep 2020 20:41:33

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:29', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '31e5d93f-58bf-448a-a6e8-8b7e34b3ed95'	System	21 Sep 2020 20:41:33
User entered '21 Sep 2020 15:41'	System	21 Sep 2020 20:41:33

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 7'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:12:52', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'af3ba9a2-ef2a-432d-ae38-a5a7ff1dcd15'	System	22 Sep 2020 17:13:20
User entered 'Yes (Y)'	System	22 Sep 2020 17:13:20

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:07', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'af3ba9a2-ef2a-432d-ae38-a5a7ff1dcd15'	System	22 Sep 2020 17:13:20
User entered '97.8'	System	22 Sep 2020 17:13:20

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:13', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'af3ba9a2-ef2a-432d-ae38-a5a7ff1dcd15'	System	22 Sep 2020 17:13:20
User entered 'No (N)'	System	22 Sep 2020 17:13:20

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:18', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'af3ba9a2-ef2a-432d-ae38-a5a7ff1dcd15'	System	22 Sep 2020 17:13:20
User entered '22 Sep 2020 12:13'	System	22 Sep 2020 17:13:20

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:54:49', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '516aa8b0-72ed-4cdd-8c82-c3c75ff20b0f' User entered 'None (1)'	System	16 Sep 2020 19:55:10
	System	16 Sep 2020 19:55:10

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:54:55', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '516aa8b0-72ed-4cdd-8c82-c3c75ff20b0f'	System	16 Sep 2020 19:55:10
User entered 'No (N)'	System	16 Sep 2020 19:55:10

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:54:58', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '516aa8b0-72ed-4cdd-8c82-c3c75ff20b0f' User entered 'No (N)'	System	16 Sep 2020 19:55:10

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:02', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '516aa8b0-72ed-4cdd-8c82-c3c75ff20b0f'	System	16 Sep 2020 19:55:10
User entered 'None (1)'	System	16 Sep 2020 19:55:10

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:06', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '516aa8b0-72ed-4cdd-8c82-c3c75ff20b0f' User entered '16 Sep 2020 14:55'	System	16 Sep 2020 19:55:10
	System	16 Sep 2020 19:55:10

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:39'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 17:09'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:09:38', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '1dd3dd00-0151-4108-b834-39f589d58749'	System	16 Sep 2020 23:09:55
User entered 'None (1)'	System	16 Sep 2020 23:09:55

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:09:35', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '1dd3dd00-0151-4108-b834-39f589d58749'	System	16 Sep 2020 23:09:55
User entered 'No (N)'	System	16 Sep 2020 23:09:55

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:09:41', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '1dd3dd00-0151-4108-b834-39f589d58749'	System	16 Sep 2020 23:09:55
User entered 'No (N)'	System	16 Sep 2020 23:09:55

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:09:48', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '1dd3dd00-0151-4108-b834-39f589d58749'	System	16 Sep 2020 23:09:55
User entered 'None (1)'	System	16 Sep 2020 23:09:55

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:09:51', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '1dd3dd00-0151-4108-b834-39f589d58749'	System	16 Sep 2020 23:09:55
User entered '16 Sep 2020 18:09'	System	16 Sep 2020 23:09:55

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 18:04'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 2'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:13', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '204fc90e-fe10-4dfe-a91b-4853943d22a1'	System	17 Sep 2020 19:06:40
User entered 'None (1)'	System	17 Sep 2020 19:06:40

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:22', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '204fc90e-fe10-4dfe-a91b-4853943d22a1'	System	17 Sep 2020 19:06:40
User entered 'No (N)'	System	17 Sep 2020 19:06:40

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:24', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '204fc90e-fe10-4dfe-a91b-4853943d22a1'	System	17 Sep 2020 19:06:40
User entered 'No (N)'	System	17 Sep 2020 19:06:40

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:30', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '204fc90e-fe10-4dfe-a91b-4853943d22a1'	System	17 Sep 2020 19:06:40
User entered 'None (1)'	System	17 Sep 2020 19:06:40

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:33', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '204fc90e-fe10-4dfe-a91b-4853943d22a1'	System	17 Sep 2020 19:06:40
User entered '17 Sep 2020 14:06'	System	17 Sep 2020 19:06:40

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 3'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:27:44', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '497fb717-e642-4c76-92ab-d326a758ef2a' User entered 'None (1)'	System	18 Sep 2020 17:28:14
	System	18 Sep 2020 17:28:14

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:27:56', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '497fb717-e642-4c76-92ab-d326a758ef2a'	System	18 Sep 2020 17:28:14
User entered 'No (N)'	System	18 Sep 2020 17:28:14

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:27:59', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '497fb717-e642-4c76-92ab-d326a758ef2a' User entered 'No (N)'	System	18 Sep 2020 17:28:14

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:09', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '497fb717-e642-4c76-92ab-d326a758ef2a' User entered 'None (1)'	System	18 Sep 2020 17:28:14

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:12', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '497fb717-e642-4c76-92ab-d326a758ef2a' User entered '18 Sep 2020 12:28'	System	18 Sep 2020 17:28:14
	System	18 Sep 2020 17:28:14

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 4'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:17', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '403581a7-c92f-40c4-ba96-56eef0c8439f'	System	19 Sep 2020 18:26:32
User entered 'None (1)'	System	19 Sep 2020 18:26:32

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:21', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '403581a7-c92f-40c4-ba96-56eef0c8439f'	System	19 Sep 2020 18:26:32
User entered 'No (N)'	System	19 Sep 2020 18:26:32

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:23', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '403581a7-c92f-40c4-ba96-56eef0c8439f'	System	19 Sep 2020 18:26:32
User entered 'No (N)'	System	19 Sep 2020 18:26:32

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:26', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '403581a7-c92f-40c4-ba96-56eef0c8439f' User entered 'None (1)'	System	19 Sep 2020 18:26:32

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:29', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '403581a7-c92f-40c4-ba96-56eef0c8439f' User entered '19 Sep 2020 13:26'	System	19 Sep 2020 18:26:32
	System	19 Sep 2020 18:26:32

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 5'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:18', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '2182c998-20c7-4195-b8f4-e875ada8c913'	System	20 Sep 2020 21:08:31
User entered 'None (1)'	System	20 Sep 2020 21:08:31

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:22', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '2182c998-20c7-4195-b8f4-e875ada8c913'	System	20 Sep 2020 21:08:31
User entered 'No (N)'	System	20 Sep 2020 21:08:31

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:24', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '2182c998-20c7-4195-b8f4-e875ada8c913'	System	20 Sep 2020 21:08:31
User entered 'No (N)'	System	20 Sep 2020 21:08:31

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:27', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '2182c998-20c7-4195-b8f4-e875ada8c913'	System	20 Sep 2020 21:08:31
User entered 'None (1)'	System	20 Sep 2020 21:08:31

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:30', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '2182c998-20c7-4195-b8f4-e875ada8c913'	System	20 Sep 2020 21:08:31
User entered '20 Sep 2020 16:08'	System	20 Sep 2020 21:08:31

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 6'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:35', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '59ca6d72-9870-4f8d-9e5e-497bd158adb1' User entered 'None (1)'	System	21 Sep 2020 20:41:51
	System	21 Sep 2020 20:41:51

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:39', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '59ca6d72-9870-4f8d-9e5e-497bd158adb1' User entered 'No (N)'	System	21 Sep 2020 20:41:51

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:41', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '59ca6d72-9870-4f8d-9e5e-497bd158adb1' User entered 'No (N)'	System	21 Sep 2020 20:41:51

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:45', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '59ca6d72-9870-4f8d-9e5e-497bd158adb1' User entered 'None (1)'	System	21 Sep 2020 20:41:51
	System	21 Sep 2020 20:41:51

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:47', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '59ca6d72-9870-4f8d-9e5e-497bd158adb1' User entered '21 Sep 2020 15:41'	System	21 Sep 2020 20:41:51
	System	21 Sep 2020 20:41:51

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 7'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:23', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'daab9016-8f64-4948-a4ab-e4a4d1948bd2'	System	22 Sep 2020 17:13:42
User entered 'None (1)'	System	22 Sep 2020 17:13:42

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:27', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'daab9016-8f64-4948-a4ab-e4a4d1948bd2'	System	22 Sep 2020 17:13:42
User entered 'No (N)'	System	22 Sep 2020 17:13:42

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:30', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'daab9016-8f64-4948-a4ab-e4a4d1948bd2'	System	22 Sep 2020 17:13:42
User entered 'No (N)'	System	22 Sep 2020 17:13:42

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:37', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'daab9016-8f64-4948-a4ab-e4a4d1948bd2'	System	22 Sep 2020 17:13:42
User entered 'None (1)'	System	22 Sep 2020 17:13:42

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:40', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'daab9016-8f64-4948-a4ab-e4a4d1948bd2'	System	22 Sep 2020 17:13:42
User entered '22 Sep 2020 12:13'	System	22 Sep 2020 17:13:42

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:14', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c9132915-07e8-46b2-aec4-6b4f2cf1c993'	System	16 Sep 2020 19:55:40
User entered 'None (0)'	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:18', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c9132915-07e8-46b2-aec4-6b4f2cf1c993'	System	16 Sep 2020 19:55:40
User entered 'None (0)'	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:20', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c9132915-07e8-46b2-aec4-6b4f2cf1c993'	System	16 Sep 2020 19:55:40
User entered 'None (0)'	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:23', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c9132915-07e8-46b2-aec4-6b4f2cf1c993'	System	16 Sep 2020 19:55:40
User entered 'None (0)'	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:25', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c9132915-07e8-46b2-aec4-6b4f2cf1c993'	System	16 Sep 2020 19:55:40
User entered 'None (0)'	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:28', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c9132915-07e8-46b2-aec4-6b4f2cf1c993'	System	16 Sep 2020 19:55:40
User entered 'None (0)'	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:31', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c9132915-07e8-46b2-aec4-6b4f2cf1c993'	System	16 Sep 2020 19:55:40
User entered 'No (N)'	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T14:55:37', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c9132915-07e8-46b2-aec4-6b4f2cf1c993'	System	16 Sep 2020 19:55:40
User entered '16 Sep 2020 14:55'	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:39'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 17:09'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:09:57', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6841b5ec-cf02-47f1-b625-aba97ba7c9a8'	System	16 Sep 2020 23:10:23
User entered 'None (0)'	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:09:59', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6841b5ec-cf02-47f1-b625-aba97ba7c9a8'	System	16 Sep 2020 23:10:23
User entered 'None (0)'	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:10:01', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6841b5ec-cf02-47f1-b625-aba97ba7c9a8'	System	16 Sep 2020 23:10:23
User entered 'None (0)'	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:10:07', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6841b5ec-cf02-47f1-b625-aba97ba7c9a8'	System	16 Sep 2020 23:10:23
User entered 'None (0)'	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:10:10', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6841b5ec-cf02-47f1-b625-aba97ba7c9a8'	System	16 Sep 2020 23:10:23
User entered 'None (0)'	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:10:12', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6841b5ec-cf02-47f1-b625-aba97ba7c9a8'	System	16 Sep 2020 23:10:23
User entered 'None (0)'	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:10:18', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6841b5ec-cf02-47f1-b625-aba97ba7c9a8'	System	16 Sep 2020 23:10:23
User entered 'No (N)'	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-16T18:10:21', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6841b5ec-cf02-47f1-b625-aba97ba7c9a8'	System	16 Sep 2020 23:10:23
User entered '16 Sep 2020 18:10'	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 18:04'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 2'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:38', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ede90c88-55e7-4ff9-8143-51cc5240493e' User entered 'None (0)'	System	17 Sep 2020 19:07:06
	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:40', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ede90c88-55e7-4ff9-8143-51cc5240493e' User entered 'None (0)'	System	17 Sep 2020 19:07:06
	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:42', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ede90c88-55e7-4ff9-8143-51cc5240493e' User entered 'None (0)'	System	17 Sep 2020 19:07:06
	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:44', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ede90c88-55e7-4ff9-8143-51cc5240493e' User entered 'None (0)'	System	17 Sep 2020 19:07:06
	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:46', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ede90c88-55e7-4ff9-8143-51cc5240493e' User entered 'None (0)'	System	17 Sep 2020 19:07:06
	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:49', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ede90c88-55e7-4ff9-8143-51cc5240493e' User entered 'None (0)'	System	17 Sep 2020 19:07:06
	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:52', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ede90c88-55e7-4ff9-8143-51cc5240493e' User entered 'No (N)'	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-17T14:06:59', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ede90c88-55e7-4ff9-8143-51cc5240493e' User entered '17 Sep 2020 14:06'	System	17 Sep 2020 19:07:06
	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 3'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:16', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '932d1205-188b-411a-b04d-6c2229eac0c9'	System	18 Sep 2020 17:28:45
User entered 'None (0)'	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:20', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '932d1205-188b-411a-b04d-6c2229eac0c9'	System	18 Sep 2020 17:28:45
User entered 'None (0)'	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:24', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '932d1205-188b-411a-b04d-6c2229eac0c9'	System	18 Sep 2020 17:28:45
User entered 'None (0)'	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:27', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '932d1205-188b-411a-b04d-6c2229eac0c9'	System	18 Sep 2020 17:28:45
User entered 'None (0)'	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:33', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '932d1205-188b-411a-b04d-6c2229eac0c9'	System	18 Sep 2020 17:28:45
User entered 'None (0)'	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:35', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '932d1205-188b-411a-b04d-6c2229eac0c9'	System	18 Sep 2020 17:28:45
User entered 'None (0)'	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:38', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '932d1205-188b-411a-b04d-6c2229eac0c9'	System	18 Sep 2020 17:28:45
User entered 'No (N)'	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-18T12:28:42', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '932d1205-188b-411a-b04d-6c2229eac0c9'	System	18 Sep 2020 17:28:45
User entered '18 Sep 2020 12:28'	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 4'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:33', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '045c6867-0c59-496e-bcd9-5217938f3864'	System	19 Sep 2020 18:26:55
User entered 'None (0)'	System	19 Sep 2020 18:26:55

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:35', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '045c6867-0c59-496e-bcd9-5217938f3864'	System	19 Sep 2020 18:26:55
User entered 'None (0)'	System	19 Sep 2020 18:26:55

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:37', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '045c6867-0c59-496e-bcd9-5217938f3864'	System	19 Sep 2020 18:26:55
User entered 'None (0)'	System	19 Sep 2020 18:26:55

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:39', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '045c6867-0c59-496e-bcd9-5217938f3864'	System	19 Sep 2020 18:26:55
User entered 'None (0)'	System	19 Sep 2020 18:26:55

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:42', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '045c6867-0c59-496e-bcd9-5217938f3864'	System	19 Sep 2020 18:26:55
User entered 'None (0)'	System	19 Sep 2020 18:26:55

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:45', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '045c6867-0c59-496e-bcd9-5217938f3864'	System	19 Sep 2020 18:26:55
User entered 'None (0)'	System	19 Sep 2020 18:26:55

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:48', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '045c6867-0c59-496e-bcd9-5217938f3864'	System	19 Sep 2020 18:26:55
User entered 'No (N)'	System	19 Sep 2020 18:26:55

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-19T13:26:50', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '045c6867-0c59-496e-bcd9-5217938f3864' User entered '19 Sep 2020 13:26'	System	19 Sep 2020 18:26:55
	System	19 Sep 2020 18:26:55

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 5'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:34', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8772a3ea-894c-4a4e-8f6d-7dab422656bb' User entered 'None (0)'	System	20 Sep 2020 21:08:58
	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:37', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8772a3ea-894c-4a4e-8f6d-7dab422656bb' User entered 'None (0)'	System	20 Sep 2020 21:08:58
	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:40', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8772a3ea-894c-4a4e-8f6d-7dab422656bb' User entered 'None (0)'	System	20 Sep 2020 21:08:58
	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:41', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8772a3ea-894c-4a4e-8f6d-7dab422656bb' User entered 'None (0)'	System	20 Sep 2020 21:08:58
	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:44', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8772a3ea-894c-4a4e-8f6d-7dab422656bb' User entered 'None (0)'	System	20 Sep 2020 21:08:58
	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:47', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8772a3ea-894c-4a4e-8f6d-7dab422656bb' User entered 'None (0)'	System	20 Sep 2020 21:08:58
	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:52', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8772a3ea-894c-4a4e-8f6d-7dab422656bb' User entered 'No (N)'	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-20T16:08:55', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8772a3ea-894c-4a4e-8f6d-7dab422656bb' User entered '20 Sep 2020 16:08'	System	20 Sep 2020 21:08:58
	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 6'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:52', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '54e865de-2f38-4dd1-8b12-5f48354beb64' User entered 'None (0)'	System	21 Sep 2020 20:42:17
	System	21 Sep 2020 20:42:17

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:54', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '54e865de-2f38-4dd1-8b12-5f48354beb64' User entered 'None (0)'	System	21 Sep 2020 20:42:17
	System	21 Sep 2020 20:42:17

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:41:59', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '54e865de-2f38-4dd1-8b12-5f48354beb64' User entered 'None (0)'	System	21 Sep 2020 20:42:17
	System	21 Sep 2020 20:42:17

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:42:01', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '54e865de-2f38-4dd1-8b12-5f48354beb64' User entered 'None (0)'	System	21 Sep 2020 20:42:17
	System	21 Sep 2020 20:42:17

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:42:04', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '54e865de-2f38-4dd1-8b12-5f48354beb64' User entered 'None (0)'	System	21 Sep 2020 20:42:17
	System	21 Sep 2020 20:42:17

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:42:06', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '54e865de-2f38-4dd1-8b12-5f48354beb64' User entered 'None (0)'	System	21 Sep 2020 20:42:17
	System	21 Sep 2020 20:42:17

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:42:11', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '54e865de-2f38-4dd1-8b12-5f48354beb64' User entered 'No (N)'	System	21 Sep 2020 20:42:17

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-21T15:42:14', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '54e865de-2f38-4dd1-8b12-5f48354beb64' User entered '21 Sep 2020 15:42'	System	21 Sep 2020 20:42:17
	System	21 Sep 2020 20:42:17

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 7'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:45', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ab803fb5-2951-4174-b218-0964af19c2be'	System	22 Sep 2020 17:14:10
User entered 'None (0)'	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:47', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ab803fb5-2951-4174-b218-0964af19c2be'	System	22 Sep 2020 17:14:10
User entered 'None (0)'	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:50', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ab803fb5-2951-4174-b218-0964af19c2be'	System	22 Sep 2020 17:14:10
User entered 'None (0)'	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:52', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ab803fb5-2951-4174-b218-0964af19c2be'	System	22 Sep 2020 17:14:10
User entered 'None (0)'	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:55', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ab803fb5-2951-4174-b218-0964af19c2be'	System	22 Sep 2020 17:14:10
User entered 'None (0)'	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:13:58', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ab803fb5-2951-4174-b218-0964af19c2be'	System	22 Sep 2020 17:14:10
User entered 'None (0)'	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:14:03', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ab803fb5-2951-4174-b218-0964af19c2be'	System	22 Sep 2020 17:14:10
User entered 'No (N)'	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-09-22T12:14:08', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'ab803fb5-2951-4174-b218-0964af19c2be'	System	22 Sep 2020 17:14:10
User entered '22 Sep 2020 12:14'	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:42:05

US3552444

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:29:57

US3552444

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:29:57

US3552444

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	23 Sep 2020 17:29:57

US3552444

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 17:29:57

US3552444

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Sep 2020 16:48:23

US3552444

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:48:23

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Sep 2020 16:48:33

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 16:48:33

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	30 Sep 2020 16:48:33

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 16:48:33

US3552444

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:14:10

US3552444

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 17:14:10

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:14:19

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Nov 2020 20:04:09
User entered '7 Oct 2020'	Stanley Dublin (b) (4)	07 Oct 2020 17:14:19

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	07 Oct 2020 17:14:19

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	07 Oct 2020 17:14:19

US3552444

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:34:09

US3552444

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 12:34:09

US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:34:52

US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:34:52

US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:34:52

US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	15 Oct 2020 12:34:52

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '11:36'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:36'	System	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '95'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '16'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '109'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '68'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:45

US3552444

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:42:45

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Is dose was withdrawn due to an AE (worsening arrhythmia) , please update to say "AE", not PI decision and remove comment below . Thank you! ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:52:54
Query 'Is dose was withdrawn due to an AE (worsening arrhythmia) , please update to say "AE", not PI decision and remove comment below . Thank you! ' answered with 'updated per query request' (Site from CRA).	Cassandra Zehenny (b) (4)	16 Oct 2020 18:32:41
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	16 Oct 2020 18:32:32
User opened query 'Is dose was withdrawn due to an AE (worsening arrhythmia) , please update to say "AE", not PI decision and remove comment below . Thank you! ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 16:38:05
User entered 'Physician Decision (PHYSICIAN DECISION)'	Stanley Dublin (b) (4)	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User closed query 'Please add AE to this line - WORSENING OF ARRHYTHMIA' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:10:03
Query 'Please add AE to this line - WORSENING OF ARRHYTHMIA' answered with 'done' (Site from CRA).	Cassandra Zehenny (b) (4)	18 Nov 2020 16:01:37
User entered 'worsening of arrhythmia' reason for change: Per Query Resolution	(b) (4)	18 Nov 2020 16:01:31
User opened query 'Please add AE to this line - WORSENING OF ARRHYTHMIA' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 02:38:06
User entered empty; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	16 Oct 2020 18:32:32
User entered 'given instability of cardiac disease, will not give 2nd vaccine'	Stanley Dublin (b) (4)	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:54

US3552444

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:54

US3552444

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:54'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:54

US3552444

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:54'	System	15 Oct 2020 12:44:54

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '11:59'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 16:41:00

US3552444

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:41:00

US3552444

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 16:41:08

US3552444

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 16:41:08

US3552444

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 16:41:08

US3552444

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 16:41:08

US3552444

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:41:26

US3552444

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:41:26

US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:41:34

US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:41:34

US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	28 Oct 2020 15:41:34

US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Oct 2020 15:41:34

US3552444

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	06 Nov 2020 15:35:22
User entered 'No (N)'	Mikayla Frye (b) (4)	06 Nov 2020 15:35:13

US3552444

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 15:35:22
User entered empty.	System	06 Nov 2020 15:35:13

US3552444

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	06 Nov 2020 15:35:32

US3552444

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Nov 2020 20:04:21
User entered '6 Nov 2020'	Mikayla Frye (b) (4)	06 Nov 2020 15:35:32

US3552444

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	06 Nov 2020 15:35:32

US3552444

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	06 Nov 2020 15:35:32

US3552444

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:09

US3552444

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 17:42:09

US3552444

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:19

US3552444

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:19

US3552444

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:19

US3552444

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:33

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	11 Nov 2020 17:42:19

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:30

US3552444

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:30

US3552444

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:42

US3552444

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:42

US3552444

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:38'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:42

US3552444

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 09:38'	System	11 Nov 2020 17:42:42

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered 'Day 64'	System	16 Sep 2020 19:42:05

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-11-17T17:26:25', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a566e1f9-750c-448d-9640-26ef056c9cda' User entered 'No (N)'	System	17 Nov 2020 23:26:44

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

Have you been exposed to someone with 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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-11-17T17:26:31', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a566e1f9-750c-448d-9640-26ef056c9cda'	System	17 Nov 2020 23:26:44
User entered 'No (N)'	System	17 Nov 2020 23:26:44

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-11-17T17:26:42', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a566e1f9-750c-448d-9640-26ef056c9cda' User entered '17 Nov 2020 17:26:42'	System	17 Nov 2020 23:26:44
	System	17 Nov 2020 23:26:44

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 19:42:05

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 19:42:05
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 19:42:05

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '13 Nov 2020 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '17 Nov 2020 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-11-23T14:21:39', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '05c47e82-8103-43f3-8ccd-032da57fa94d'	System	23 Nov 2020 20:21:56
User entered 'No (N)'	System	23 Nov 2020 20:21:56

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

Have you been exposed to someone with 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 (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-11-23T14:21:43', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '05c47e82-8103-43f3-8ccd-032da57fa94d'	System	23 Nov 2020 20:21:56
User entered 'No (N)'	System	23 Nov 2020 20:21:56

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2020-11-23T14:21:51', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '05c47e82-8103-43f3-8ccd-032da57fa94d' User entered '23 Nov 2020 14:21:51'	System	23 Nov 2020 20:21:56
	System	23 Nov 2020 20:21:56

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 09:01:49

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:01:49
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 09:01:49

US3552444

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:34:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:31:57

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Epistaxis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 15:14:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 15:14:32
Data point term sent to Coder	System	15 Oct 2020 14:34:18
User entered 'epistaxis'	Mikayla Frye (b) (4)	15 Oct 2020 14:33:56
	(b) (4)	

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '11 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[None](#)

Audit	User	Time (GMT)
User entered '1'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE and please update to specify the type of Arrhythmia. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:43:59
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 01:40:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 01:40:55
Data point term sent to Coder	System	16 Nov 2020 16:32:36
Query 'Per DM CLR: Please review AE and please update to specify the type of Arrhythmia. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	16 Nov 2020 16:32:14
Coding entries removed.	Cassandra Zehenny (b) (4)	16 Nov 2020 16:32:00
User entered 'WORSENING atrial fibrillation ARRHYTHMIA' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	16 Nov 2020 16:32:00
User opened query 'Per DM CLR: Please review AE and please update to specify the type of Arrhythmia. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:14:59
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 16:10:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 16:10:11
Data point term sent to Coder	System	15 Oct 2020 14:35:20
User entered 'worsening arrhythmia'	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '01 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Nov 2020 20:04:38
User entered '1 Oct 2020'	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	28 Oct 2020 15:42:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	28 Oct 2020 15:42:21
User entered empty.	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: As "Worsening of Arrhythmia" is the reason for Dosing Discontinuation, Please consider to update the data for action taken with Investigational product as "Investigational product withdrawn". Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 01:55:52
Query 'Per CDM: As "Worsening of Arrhythmia" is the reason for Dosing Discontinuation, Please consider to update the data for action taken with Investigational product as "Investigational product withdrawn". Thank you.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	04 Nov 2020 15:29:33
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	04 Nov 2020 15:29:26
User opened query 'Per CDM: As "Worsening of Arrhythmia" is the reason for Dosing Discontinuation, Please consider to update the data for action taken with Investigational product as "Investigational product withdrawn". Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:42:11
User entered 'None (NONE)'	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	28 Oct 2020 15:42:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:34:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 14:34:44

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:34:33

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:42:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:45:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:45:39
Data point term sent to Coder	System	17 Sep 2020 13:44:11
User entered 'claritin'	Stanley Dublin (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal allergies'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	03 Nov 2020 15:46:00
User entered '1'	Stanley Doublin (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:39:11
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	03 Nov 2020 15:46:12
User entered 'mg (mg)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	03 Nov 2020 15:46:00
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:50:39
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:43:39

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[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 PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:48:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:48:34
Data point term sent to Coder	System	17 Sep 2020 13:47:16
User entered 'advair'	Stanley Doublin (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'asthma'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 02:09:35
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'subject reported data' (Site from DM).	Cassandra Zehenny (b) (4)	03 Nov 2020 15:46:27
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:50:56
User entered '1'	Stanley Dublin (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'puff'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Sep 2020 15:11:04
User entered 'un UNK 1990' reason for change: Data Entry Error	Stanley Dublin (b) (4)	17 Sep 2020 15:11:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Sep 2020 13:47:16
User entered ' 1990' (non-conformant).	Stanley Dublin (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:47:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:50:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:50:32
Data point term sent to Coder	System	17 Sep 2020 13:49:20
User entered 'doxazosin'	Stanley Dublin (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'benign prostatic hypertrophy'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '8'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 13:58:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 13:58:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	17 Sep 2020 13:58:24
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 13:49:16
User entered empty.	Stanley Dublin (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 13:58:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 13:58:24
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	17 Sep 2020 13:58:24
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 13:49:16
User entered empty.	Stanley Doublin (b) (4)	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:49:16

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:51:35
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 Sep 2020 13:51:35
Data point term sent to Coder	System	17 Sep 2020 13:50:21
User entered 'atenolol'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'atrial fibrillation'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the MH-ATRIAL FIBRILLATION-UN UNK 2019. Please review and reconcile the Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 02:09:46
Query 'Per DM CLR: The Con Med start date is prior to the start date of the MH-ATRIAL FIBRILLATION-UN UNK 2019. Please review and reconcile the Con Med and MH start dates as appropriate. ' answered with 'subject reported data in this way.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:48:55
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the MH-ATRIAL FIBRILLATION-UN UNK 2019. Please review and reconcile the Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:51:10
User entered 'un UNK 2010'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	15 Oct 2020 12:35:34
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	15 Oct 2020 12:35:34
User entered empty.	Stanley Dublin (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:50:02

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:54:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:54:34
Data point term sent to Coder	System	17 Sep 2020 13:53:25
User entered 'finasteride'	Stanley Doublin (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'benign prostatic hypertrophy'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response to 'If frequency is Other, specify' is entered as 'EVERY OTHER DAY'; however, corresponding data is present in the dropdown. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:27:41
Query 'Per CDM: Response to 'If frequency is Other, specify' is entered as 'EVERY OTHER DAY'; however, corresponding data is present in the dropdown. Please review and update accordingly.' answered with 'Resolved per query request' (Site from DM).	Cassandra Zehenny (b) (4)	21 Oct 2020 14:51:25
User entered 'every other day (QOD)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:51:22
User opened query 'Per CDM: Response to 'If frequency is Other, specify' is entered as 'EVERY OTHER DAY'; however, corresponding data is present in the dropdown. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:28:29
User entered 'other (OTHER)'	Stanley Doublin (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	21 Oct 2020 14:51:22
User entered 'every other day'	Stanley Dublin (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:51:22
User entered empty.	System	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 14:51:22
User entered empty.	System	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 14:51:22
User entered empty.	System	17 Sep 2020 13:52:31

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[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)	17 Sep 2020 13:55:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:55:37
Data point term sent to Coder	System	17 Sep 2020 13:54:26
User entered 'atorvastatin'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:53:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:56:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:56:40
Data point term sent to Coder	System	17 Sep 2020 13:55:27
User entered 'nexium'	Stanley Dublin (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'gastroesophageal reflux disease'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:54:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:57:32
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 Sep 2020 13:57:32
Data point term sent to Coder	System	17 Sep 2020 13:56:30
User entered 'lisinopril'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	28 Oct 2020 15:48:30
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Nov 2020 20:05:20
User entered '7 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	28 Oct 2020 15:48:30
User entered empty.	Stanley Dublin (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:55:38

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:57:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:57:32
Data point term sent to Coder	System	17 Sep 2020 13:56:31
User entered 'tadalafil'	Stanley Dublin (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'benign prostatic hypertrophy'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:56:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 15:50:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 15:50:20
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	03 Nov 2020 15:49:31 03 Nov 2020 15:49:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:58:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:58:39
Data point term sent to Coder User entered 'melatonin'	System Stanley Doublin (b) (4)	17 Sep 2020 13:57:33 17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g insomnia etc). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:55:14
Query 'Per DM CLR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g insomnia etc). Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	03 Nov 2020 15:50:24
User entered 'insomnia' reason for change: Per Query Resolution	(b) (4)	03 Nov 2020 15:49:13
User opened query 'Per DM CLR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g insomnia etc). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:51:50
User entered 'sleep aid'	Stanley Doublin (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:57:05

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[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: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:59:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:59:33
Data point term sent to Coder	System	17 Sep 2020 13:58:39
User entered 'eliquis'	Stanley Dublin (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	03 Nov 2020 15:50:41
User entered 'No (N)'	Stanley Doublin (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = PCOAGULATION PREVENTION, however the column for "Prophylaxis"=No. Please reconcile and update as appropriate ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:59:58
Query 'Per DM CLR: Indication = PCOAGULATION PREVENTION, however the column for "Prophylaxis"=No. Please reconcile and update as appropriate ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:50:47
User opened query 'Per DM CLR: Indication = PCOAGULATION PREVENTION, however the column for "Prophylaxis"=No. Please reconcile and update as appropriate ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:52:02
User entered 'coagulation prevention'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 13:57:54

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 13:10:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 13:10:02
Data point term sent to Coder	System	15 Oct 2020 12:40:00
User entered 'cefalexin'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'tooth extraction'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 12:39:49

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 12:41:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 12:41:34
Data point term sent to Coder User entered 'tylenol'	System Stanley Doublin (b) (4)	15 Oct 2020 12:41:01 15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'tooth extraction'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '325'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 12:41:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 12:41:35
Data point term sent to Coder	System	15 Oct 2020 12:41:01
User entered 'atenolol'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'atrial fibrillation'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 12:41:01

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[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)	29 Oct 2020 18:15:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:15:23
Data point term sent to Coder	System	28 Oct 2020 15:44:17
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'prophylaxis'	Stanley Doublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Doublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'injection'	Stanley Doublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Dublin (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:34:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:44:13

US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:34:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	02 Nov 2020 17:24:12
	(b) (4)	

US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:34:33

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:01
	(b) (4)	

US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:34:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Tooth Extraction'	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:01
	(b) (4)	

US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:34:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'Medical History (MH)'	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:01
	(b) (4)	

US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:34:33

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:01
	(b) (4)	

US3552444

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:33

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Joan Siegner (b) (4)	15 Oct 2020 13:23:36

US3552444

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:33

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	Joan Siegner (b) (4)	15 Oct 2020 13:23:36

US3552444

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:33

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:32:41
User closed query 'Please update to AE#3 (actual line item for this AE) ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:53:58
Query 'Please update to AE#3 (actual line item for this AE) ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	19 Nov 2020 19:37:48
User entered 'AE #3' reason for change: Per Query Resolution	Heather Douds (b) (4)	19 Nov 2020 19:37:43
User opened query 'Please update to AE#3 (actual line item for this AE) ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:47:57
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	18 Nov 2020 17:46:22
User entered 'AE #2' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	18 Nov 2020 17:46:18
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:18:15
Query 'Please check spelling ' canceled (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:44:37
User opened query 'Please check spelling ' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:43:36
User entered 'worsening of arrhythmia'	Joan Siegner (b) (4)	15 Oct 2020 13:23:36