

US3552444 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:54:28

All time stamps listed in this document are displayed in GMT

US3552444

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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[Participant ID](#)

US3552444

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

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US3552444

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3552444

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3552444

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3552444

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3552444

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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Were any significant conditions reported?

Yes ☒  
No ☐

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US3552444

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1954
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1954
Start Year (derived)	1954
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3552444

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	LEFT SHOULDER PAIN
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN 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

US3552444

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1954
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1954
Start Year (derived)	1954
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552444

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	L4 L5 BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3552444

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	LEFT TOTAL KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 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

US3552444

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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



US3552444

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3552444

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	CHRONIC SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1954
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1954
Start Year (derived)	1954
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552444

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552444

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Condition	DENTAL DECAY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
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

US3552444

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3552444

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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.*

US3552444

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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**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 ☐

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**Specify**

US3552444

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

**Location and Living Circumstances Risk (check all that apply)**

<b>No Risk Identified</b>	False
<b>Resides in Nursing Home or Assisted Living Facility</b>	False
<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

US3552444

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

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 ☒

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Height	ND - Not Done
Weight	ND - Not Done

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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



US3552444

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

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 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

13:50 (24 HR)

Collection date and time (derived)

16 SEP 2020 13:50

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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		

US3552444

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

**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

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

**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

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:54:28

**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



US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28

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: 11 Aug 2021 22:54:28

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 1977

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:54:28

Yes <input type="checkbox"/>	
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: 11 Aug 2021 22:54:28

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 ☒

PRODUCTION RELEASE (v12.003

59 of 1977

EAB) (1725)

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

Yes <input type="checkbox"/>	
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: 11 Aug 2021 22:54:28

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

61 of 1977

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:54:28

Yes <input type="checkbox"/>	
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: 11 Aug 2021 22:54:28

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 ☒

PRODUCTION RELEASE (v12.003

63 of 1977

EAB) (1725)



US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:54:28

		Yes <input type="checkbox"/>
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: 11 Aug 2021 22:54:28

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 ☒

PRODUCTION RELEASE (v12.003

65 of 1977

EAB) (1725)

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:54:28

Yes <input type="checkbox"/>	
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: 11 Aug 2021 22:54:28

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

67 of 1977

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

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

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:22:14

Generated On: 11 Aug 2021 22:54:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:22:14

Generated On: 11 Aug 2021 22:54:28

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 \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3552444

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:22:14

Generated On: 11 Aug 2021 22:54:28

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

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 NOV 2020

Collection time (00:00-23:59)

09:38 (24 HR)

Collection date and time (derived)

11 NOV 2020 09:38

US3552444

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:22:13

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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: 11 Aug 2021 22:54:28

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 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: 11 Aug 2021 22:54:28

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 10:02:59
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: 11 Aug 2021 22:54:28

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

Date and time of submission

06 DEC 2020 12:30:20

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: 11 Aug 2021 22:54:28

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 09:03:53
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: 11 Aug 2021 22:54:28

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 08:29:36
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: 11 Aug 2021 22:54:28

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

Date and time of submission

27 DEC 2020 12:00:49

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: 11 Aug 2021 22:54:28

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 11:59:40
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: 11 Aug 2021 22:54:28

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

Date and time of submission

10 JAN 2021 12:01:22

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: 11 Aug 2021 22:54:28

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 12:28:53
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: 11 Aug 2021 22:54:28

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

Date and time of submission

22 JAN 2021 08:04:58

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: 11 Aug 2021 22:54:28

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

Date and time of submission

29 JAN 2021 12:21:15

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: 11 Aug 2021 22:54:28

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

Date and time of submission

05 FEB 2021 12:28:32

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: 11 Aug 2021 22:54:28

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

Date and time of submission

12 FEB 2021 09:22:38

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: 11 Aug 2021 22:54:28

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 09:12:11
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: 11 Aug 2021 22:54:28

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

Date and time of submission

26 FEB 2021 13:16:23

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: 11 Aug 2021 22:54:28

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

Date and time of submission

05 MAR 2021 09:24:48

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: 11 Aug 2021 22:54:28

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

Date and time of submission

12 MAR 2021 07:27:11

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: 11 Aug 2021 22:54:28

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

Date and time of submission

22 MAR 2021 15:27:35

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: 11 Aug 2021 22:54:28

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

Date and time of submission

26 MAR 2021 08:05:46

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: 11 Aug 2021 22:54:28

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

Date and time of submission

02 APR 2021 07:59:15

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: 11 Aug 2021 22:54:28

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

Date and time of submission

09 APR 2021 10:52:45

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: 11 Aug 2021 22:54:28

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

Date and time of submission

16 APR 2021 07:59:57

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: 11 Aug 2021 22:54:28

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

Date and time of submission

23 APR 2021 10:06:43

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: 11 Aug 2021 22:54:28

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

Date and time of submission

01 MAY 2021 15:53:59

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: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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02 JUL 2021 00:01

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06 JUL 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

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09 JUL 2021 00:01

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13 JUL 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

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16 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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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27 JUL 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

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

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

Date and time of submission

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31 AUG 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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03 SEP 2021 00:01

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07 SEP 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

**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°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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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[Patient Cloud Open Date & Time](#)

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15 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 OCT 2021 23:59

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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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°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: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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[Patient Cloud Open Date & Time](#)

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15 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2022 23:59

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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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



US3552444

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

Date and time of submission

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09 AUG 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

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23 AUG 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



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**Folder: New Safety Follow Up Diary (1)**

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

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

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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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 ☐

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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

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

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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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04 OCT 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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11 OCT 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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

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14 OCT 2022 00:01

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18 OCT 2022 23:59

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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

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



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**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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25 OCT 2022 23:59

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

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

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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: 11 Aug 2021 22:54:28

**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: 11 Aug 2021 22:54:28**

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

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[Patient Cloud Open Date & Time](#)

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11 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 NOV 2022 23:59

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US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2022 23:59

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US3552444

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:54:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 09:25:03

US3552444

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPTED MULTIPLE CALLS  
BETWEEN 12/9 AND 12/11,  
SUBJECT DID NOT RETURN  
CALLS OR ANSWER.

*If Contact Not Made, please provide Comments*

US3552444

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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Was Contact Attempted? Yes ☒ No ☐

---

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

---

Please select one status for the follow-up contact Contact Made ☐ Contact Not Made ☒

---

Comments DIDN'T RETURN ANY OF THE 10  
MESSAGES LEFT OVER  
If Contact Not Made, please provide Comments MULTIPLE DAYS.

---

US3552444

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

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 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3552444

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:41:59

Generated On: 11 Aug 2021 22:54:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:41:59

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:14:55

Generated On: 11 Aug 2021 22:54:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:14:55

Generated On: 11 Aug 2021 22:54:28

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 \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3552444

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:14:55

Generated On: 11 Aug 2021 22:54:28

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:14:55

Generated On: 11 Aug 2021 22:54:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 MAR 2021

Collection time (00:00-23:59)

09:31 (24 HR)

Collection date and time (derived)

31 MAR 2021 09:31

US3552444

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:14:55

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3552444**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:54:28**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552444

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:28

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3552444

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:54:28

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	25 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:41:59

Generated On: 11 Aug 2021 22:54:28

Date of updated informed consent (dd MMM yyyy)	25 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	25 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	09:14 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 09:14
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 10:05
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	53 mmHg
Diastolic Blood Pressure units	MMHG



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

25 JAN 2021

---

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

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US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 JAN 2021

What was the treatment time? (00:00-23:59) 09:35 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 09:35

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

What was the frequency of the study treatment dosing? ONCE

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

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00-23:59)	08:05 (24 HR)
Collection date and time (derived)	25 JAN 2021 08:05

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00 - 23:59)	08:11
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Collection Date and Time (derived)	25 JAN 2021 08:11
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US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

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Was Contact Attempted? Yes ☒ No ☐

---

Date of Contact or Contact Attempt (dd MMM yyyy) 1 FEB 2021

---

Please select one status for the follow-up contact Contact Made ☐ Contact Not Made ☒

---

Comments SUBJECT DID NOT ANSWER OR  
RETURN CALLS IN SPITE OF  
If Contact Not Made, please provide Comments MULTIPLE ATTEMPTS

---

US3552444

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:21:46

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3552444

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:04:13

Generated On: 11 Aug 2021 22:54:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 17:04:13

Generated On: 11 Aug 2021 22:54:28

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 MAR 2021
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 10:30
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 17:04:13

Generated On: 11 Aug 2021 22:54:28

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	5 MAR 2021
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 11:31
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3552444

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 17:04:13

Generated On: 11 Aug 2021 22:54:28

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

5 MAR 2021

---

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

---

US3552444

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 17:04:13

Generated On: 11 Aug 2021 22:54:28

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 5 MAR 2021

What was the treatment time? (00:00-23:59) 11:01 (24 HR)

Treatment Date and Time (derived) 5 MAR 2021 11:01

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

US3552444

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:04:13

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:41:59

Generated On: 11 Aug 2021 22:54:28

---

Was Contact Attempted? Yes ☒ No ☐

---

Date of Contact or Contact Attempt (dd MMM yyyy) 11 MAR 2021

---

Please select one status for the follow-up contact Contact Made ☐ Contact Not Made ☒

---

Comments ATTEMPTED MULTIPLE CALLS  
AND LEFT THREE VOICEMAILS  
*If Contact Not Made, please provide Comments* BUT NEVER RECEIVED RETURN  
CALL

---

US3552444

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:41:59

Generated On: 11 Aug 2021 22:54:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552444

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:14:54

Generated On: 11 Aug 2021 22:54:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57



US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:14:55

Generated On: 11 Aug 2021 22:54:28

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 \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3552444

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:14:54

Generated On: 11 Aug 2021 22:54:28

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:14:54

Generated On: 11 Aug 2021 22:54:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	31 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:31 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	31 MAR 2021 09:31
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US3552444

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

---

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)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

AEID	
Adverse event	EPISTAXIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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324 of 1977

EAB) (1725)

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003

326 of 1977

EAB) (1725)

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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



US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

---

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)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

329 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

331 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

333 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

335 of 1977



US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

337 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

339 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

341 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

343 of 1977



US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Name of Medication	TADALAFIL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BENIGN PROSTATIC HYPERTROPHY
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

345 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

347 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

349 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

351 of 1977



US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

353 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

355 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA 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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

357 of 1977

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3552444

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

Procedure/Surgery date ( <i>dd MMM</i> <i>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

Data signed: (b) (4) 21 Feb 2021 19:21:45

Generated On: 11 Aug 2021 22:54:28

---

Date of dosing discontinuation (dd MMM yyyy) 14 OCT 2020

---

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

---

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: 11 Aug 2021 22:54:28

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: 11 Aug 2021 22:54:28**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'US3552444'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 18:44:32

US3552444

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:18:17

US3552444

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 18:44:33

US3552444

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:18:17



US3552444

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'SCRN'	System	17 Sep 2020 13:18:17

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered (b) (6) 1946'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 18:44:35

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '74'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'YEARS'	System	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '74'	System	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Male (M)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45



US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '0'	Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45

US3552444

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:28

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:19:45



US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Sep 2020'	System	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2020'	System	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:41:25

US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:41:25



US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 18:44:33

US3552444

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'l'	System	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:54:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 1954'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50



US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 1954'	System	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '1954'	System	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:26:50

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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) (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) (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) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un Jun 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11



US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jun 2020'	System	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2020'	System	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Aug 2020'	System	17 Sep 2020 13:27:11

US3552444

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2020'	System	17 Sep 2020 13:27:11



US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	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) (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) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 1954'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 1954'	System	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '1954'	System	17 Sep 2020 13:27:36



US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:27:36

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	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

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:27:47



US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2015'	System	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2015'	System	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:27:47

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 1990'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:28:23



US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 1990'	System	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '1990'	System	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:28:23

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:54:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 1990'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43



US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 1990'	System	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '1990'	System	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:29:43

US3552444

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:29:43



US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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) (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) (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) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2018'	System	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2018'	System	17 Sep 2020 13:30:07



US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2018'	System	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2018'	System	17 Sep 2020 13:30:07

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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)	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 'left total knee replacement'	Stanley Doublin (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2010'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2010'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:30:54



US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2010'	System	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2010'	System	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2010'	System	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2010'	System	17 Sep 2020 13:30:54

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	(b) (4) 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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10



US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2019'	System	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2019'	System	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:31:10

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2000'	System	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2000'	System	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:31:48

US3552444

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:31:48



US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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 13:32:52
User entered 'skin cancer'	Stanley Doublin (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2019'	System	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2019'	System	17 Sep 2020 13:32:07



US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2019'	System	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2019'	System	17 Sep 2020 13:32:07

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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 Doublin (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 1954'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:32:47



US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 1954'	System	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '1954'	System	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:32:47

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User coded data point as SOC: Vascular disorders, HLT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	(b) (4) 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) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30



US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2015'	System	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2015'	System	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:33:30

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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) (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) (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) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2010'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51



US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2010'	System	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2010'	System	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:33:51

US3552444

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	17 Sep 2020 13:33:51



US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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).	(b) (4) System	02 Nov 2020 17:26:39
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (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) (b) (4)	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '13 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:26:13
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	02 Nov 2020 17:25:57

US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	02 Nov 2020 17:25:57



US3552444

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
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: 11 Aug 2021 22:54:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User coded data point as SOC: Psychiatric disorders, HLT: 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

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2019'	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:51:15



US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'Jan 2019'	System	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '2019'	System	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered empty.	System	03 Nov 2020 15:51:15

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '16 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '12:41'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered '16 Sep 2020 12:41'	System	17 Sep 2020 13:37:35



US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '74' in	(b) (4)	
	Stanley Dublin (b) (4)	17 Sep 2020 13:37:35
	(b) (4)	
DataPoint set to visible.	System	16 Sep 2020 19:41:32

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '212' lb	(b) (4) 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: 11 Aug 2021 22:54:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
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: 11 Aug 2021 22:54:28

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
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: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35



US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'bpm'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'breaths/min'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'mmHg'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User entered 'mmHg'	System	17 Sep 2020 13:37:35

US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35



US3552444

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35

US3552444

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:45

US3552444

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '16 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:37:45

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40



US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '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'	(b) (4) Stanley Dublin (b) (4)	17 Sep 2020 13:39:40



US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40

US3552444

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:23:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Sep 2020 13:39:40



US3552444

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'VISIT1'	System	17 Sep 2020 13:39:54

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 18:59:21

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
User entered '190971'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 18:59:21

US3552444

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 09 Dec 2020 05:50:47
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'done' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4) 07 Dec 2020 16:09:23
User entered 'No (N)'	Cassandra Zehenny (b) (4)	(b) (4) 07 Dec 2020 16:09:19
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	(b) (4), (b) (6) 04 Dec 2020 22:24:11
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: 11 Aug 2021 22:54:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered '16 Sep 2020'	(b) (4) 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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
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: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'bpm'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'breaths/min'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'mmHg'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'mmHg'	System	17 Sep 2020 13:41:09

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
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: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'bpm'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'breaths/min'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'mmHg'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'mmHg'	System	17 Sep 2020 13:41:41

US3552444

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:42:05



US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '14:19'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered '16 Sep 2020 14:19'	System	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'ONCE'	System	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 19:42:05

US3552444

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
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: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '16 Sep 2020'	(b) (4) 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: 11 Aug 2021 22:54:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
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: 11 Aug 2021 22:54:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	17 Sep 2020 13:42:25

US3552444

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'l'	System	23 Sep 2020 17:29:48

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'Yes (Y)'	System	16 Sep 2020 19:53:58
	System	16 Sep 2020 19:53:58



US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '98.6'	System	16 Sep 2020 19:53:58
	System	16 Sep 2020 19:53:58

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '16 Sep 2020 14:53'	System	16 Sep 2020 19:53:58
	System	16 Sep 2020 19:53:58

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'Yes (Y)'	System	16 Sep 2020 23:09:16
	System	16 Sep 2020 23:09:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '97.1'	System	16 Sep 2020 23:09:16
	System	16 Sep 2020 23:09:16



US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '16 Sep 2020 18:09'	System	16 Sep 2020 23:09:16
	System	16 Sep 2020 23:09:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'Yes (Y)'	System	17 Sep 2020 19:06:09
	System	17 Sep 2020 19:06:09

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:54:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '98.3'	System	17 Sep 2020 19:06:09
	System	17 Sep 2020 19:06:09

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '17 Sep 2020 14:06'	System	17 Sep 2020 19:06:09
	System	17 Sep 2020 19:06:09

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'Yes (Y)'	System	18 Sep 2020 17:27:40
	System	18 Sep 2020 17:27:40

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:54:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '97.6'	System	18 Sep 2020 17:27:40
	System	18 Sep 2020 17:27:40

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '18 Sep 2020 12:27'	System	18 Sep 2020 17:27:40
	System	18 Sep 2020 17:27:40



US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'Yes (Y)'	System	19 Sep 2020 18:26:13
	System	19 Sep 2020 18:26:13

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:54:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '96.8'	System	19 Sep 2020 18:26:13
	System	19 Sep 2020 18:26:13

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	System	19 Sep 2020 18:26:13
	System	19 Sep 2020 18:26:13

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '19 Sep 2020 13:26'	System	19 Sep 2020 18:26:13
	System	19 Sep 2020 18:26:13

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'Yes (Y)'	System	20 Sep 2020 21:08:16
	System	20 Sep 2020 21:08:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:54:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '97.2'	System	20 Sep 2020 21:08:16
	System	20 Sep 2020 21:08:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	System	20 Sep 2020 21:08:16
	System	20 Sep 2020 21:08:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '20 Sep 2020 16:08'	System	20 Sep 2020 21:08:16
	System	20 Sep 2020 21:08:16

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'Yes (Y)'	System	21 Sep 2020 20:41:33
	System	21 Sep 2020 20:41:33

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:54:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '97.8'	System	21 Sep 2020 20:41:33
	System	21 Sep 2020 20:41:33

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '21 Sep 2020 15:41'	System	21 Sep 2020 20:41:33
	System	21 Sep 2020 20:41:33

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-ac38-a5a7ff1ded15'	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: 11 Aug 2021 22:54:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-ac38-a5a7ff1ded15' User entered '97.8'	System	22 Sep 2020 17:13:20
	System	22 Sep 2020 17:13:20

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-ac38-a5a7ff1ded15'	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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-ac38-a5a7ff1ded15' User entered '22 Sep 2020 12:13'	System	22 Sep 2020 17:13:20
	System	22 Sep 2020 17:13:20

US3552444

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	16 Sep 2020 19:55:10

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' 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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	System	16 Sep 2020 23:09:55
	System	16 Sep 2020 23:09:55

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	System	16 Sep 2020 23:09:55
	System	16 Sep 2020 23:09:55

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '16 Sep 2020 18:09'	System	16 Sep 2020 23:09:55
	System	16 Sep 2020 23:09:55

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-fe10-4dfc-a91b-4853943d22a1' User entered 'No (N)'	System	17 Sep 2020 19:06:40
	System	17 Sep 2020 19:06:40

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-fe10-4dfc-a91b-4853943d22a1' User entered 'No (N)'	System	17 Sep 2020 19:06:40
	System	17 Sep 2020 19:06:40

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-fe10-4dfc-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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '17 Sep 2020 14:06'	System	17 Sep 2020 19:06:40
	System	17 Sep 2020 19:06:40

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	18 Sep 2020 17:28:14

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	18 Sep 2020 17:28:14

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (1)'	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: 11 Aug 2021 22:54:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	19 Sep 2020 18:26:32

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	System	20 Sep 2020 21:08:31
	System	20 Sep 2020 21:08:31

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	System	20 Sep 2020 21:08:31
	System	20 Sep 2020 21:08:31

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '20 Sep 2020 16:08'	System	20 Sep 2020 21:08:31
	System	20 Sep 2020 21:08:31

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	21 Sep 2020 20:41:51

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	21 Sep 2020 20:41:51

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-c4a4d1948bd2'	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: 11 Aug 2021 22:54:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-c4a4d1948bd2'	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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-c4a4d1948bd2' User entered 'No (N)'	System	22 Sep 2020 17:13:42
	System	22 Sep 2020 17:13:42

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:54:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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-c4a4d1948bd2'	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: 11 Aug 2021 22:54:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '22 Sep 2020 12:13'	System	22 Sep 2020 17:13:42
	System	22 Sep 2020 17:13:42

US3552444

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 19:55:40
	System	16 Sep 2020 19:55:40



US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 19:55:40
	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 19:55:40
	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 19:55:40
	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 19:55:40
	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 19:55:40
	System	16 Sep 2020 19:55:40

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 23:10:23
	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 23:10:23
	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 23:10:23
	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 23:10:23
	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 23:10:23
	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	16 Sep 2020 23:10:23
	System	16 Sep 2020 23:10:23



US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '16 Sep 2020 18:10'	System	16 Sep 2020 23:10:23
	System	16 Sep 2020 23:10:23

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	17 Sep 2020 19:07:06

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:54:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	18 Sep 2020 17:28:45
	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	18 Sep 2020 17:28:45
	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	18 Sep 2020 17:28:45
	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	18 Sep 2020 17:28:45
	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	18 Sep 2020 17:28:45
	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	18 Sep 2020 17:28:45
	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	System	18 Sep 2020 17:28:45
	System	18 Sep 2020 17:28:45

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '18 Sep 2020 12:28'	System	18 Sep 2020 17:28:45
	System	18 Sep 2020 17:28:45



US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	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: 11 Aug 2021 22:54:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	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: 11 Aug 2021 22:54:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	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: 11 Aug 2021 22:54:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	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: 11 Aug 2021 22:54:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	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: 11 Aug 2021 22:54:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	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: 11 Aug 2021 22:54:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	20 Sep 2020 21:08:58

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:54:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	21 Sep 2020 20:42:17



US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:54:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	22 Sep 2020 17:14:10
	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	22 Sep 2020 17:14:10
	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	22 Sep 2020 17:14:10
	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	22 Sep 2020 17:14:10
	System	22 Sep 2020 17:14:10



US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	22 Sep 2020 17:14:10
	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'None (0)'	System	22 Sep 2020 17:14:10
	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered 'No (N)'	System	22 Sep 2020 17:14:10
	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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' User entered '22 Sep 2020 12:14'	System	22 Sep 2020 17:14:10
	System	22 Sep 2020 17:14:10

US3552444

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:54:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '23 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:29:57



US3552444

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:29:57

US3552444

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:29:57

US3552444

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 16:48:23

US3552444

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'l'	System	30 Sep 2020 16:48:23

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 16:48:33

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '30 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 16:48:33

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 16:48:33

US3552444

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User entered 'l'	System	07 Oct 2020 17:14:10

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '07 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:04:09
User entered '7 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:14:19

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:14:19

US3552444

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:14:19

US3552444

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User entered 'l'	System	15 Oct 2020 12:34:09



US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered '14 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:34:52

US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:34:52

US3552444

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'VISIT2'	System	15 Oct 2020 12:34:52

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered '14 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
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: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'bpm'	System	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
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: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'mmHg'	System	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'mmHg'	System	15 Oct 2020 12:42:26

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:42:36



US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:42:36

US3552444

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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) (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) (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) (b) (4)	15 Oct 2020 12:44:37



US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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) (b) (4)	18 Nov 2020 16:01:37
User entered 'worsening of arrhythmia' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (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) (b) (4)	16 Oct 2020 18:32:32
User entered 'given instability of cardiac disease, will not give 2nd vaccine'	Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:44:37

US3552444

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:44:37



US3552444

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered '14 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Oct 2020 12:44:54

US3552444

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
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: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (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: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
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: 11 Aug 2021 22:54:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (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: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	15 Oct 2020 12:45:05

US3552444

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 16:41:00

US3552444

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'I'	System	21 Oct 2020 16:41:00

US3552444

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '21 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 16:41:08

US3552444

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:53
User entered 'l'	System	28 Oct 2020 15:41:26

US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '28 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:41:34

US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:41:34



US3552444

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 15:41:34

US3552444

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	06 Nov 2020 15:35:22
User entered 'No (N)'	(b) (4)	
	Mikayla Frye (b) (4)	06 Nov 2020 15:35:13
	(b) (4)	

US3552444

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'l'	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: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '06 Nov 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:04:21
User entered '6 Nov 2020'	Mikayla Frye (b) (4) (b) (4)	06 Nov 2020 15:35:32

US3552444

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'l'	System	11 Nov 2020 17:42:09

US3552444

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered '11 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:19

US3552444

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'VISIT3'	System	11 Nov 2020 17:42:19

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	11 Nov 2020 17:42:25



US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered empty.	System	11 Nov 2020 17:42:25

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59

US3552444

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59

US3552444

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:22:14
User entered '11 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 17:42:42

US3552444

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
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: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered '11 Nov 2020 09:38'	System	11 Nov 2020 17:42:42

US3552444

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:22:14
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	14 Dec 2020 18:01:00

US3552444

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'I'	System	14 Dec 2020 18:01:00

US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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
	System	17 Nov 2020 23:26:44



US3552444

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:27:02
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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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' 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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2020-11-27T10:02:39', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '605d3dbc-617b-41a3-898f-423bebfcdc5f' User entered 'No (N)'	System	27 Nov 2020 16:03:03

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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: '2020-11-27T10:02:48', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '605d3dbc-617b-41a3-898f-423bebfcdc5f' User entered 'No (N)'	System	27 Nov 2020 16:03:03

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2020-11-27T10:02:59', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '605d3dbc-617b-41a3-898f-423bebfcdc5f' User entered '27 Nov 2020 10:02:59'	System	27 Nov 2020 16:03:03
	System	27 Nov 2020 16:03:03

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2020-12-06T12:30:05', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c8b50085-2447-4d7d-8ef8-9eb860f4b318' User entered 'No (N)'	System	06 Dec 2020 18:30:23
	System	06 Dec 2020 18:30:23

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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: '2020-12-06T12:30:12', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c8b50085-2447-4d7d-8ef8-9eb860f4b318' User entered 'No (N)'	System	06 Dec 2020 18:30:23
	System	06 Dec 2020 18:30:23

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2020-12-06T12:30:20', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'c8b50085-2447-4d7d-8ef8-9eb860f4b318' User entered '06 Dec 2020 12:30:20'	System	06 Dec 2020 18:30:23
	System	06 Dec 2020 18:30:23

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2020-12-11T09:03:46', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'fdcf62e-ef74-4258-adf0-c15c6e33b228' User entered 'No (N)'	System	11 Dec 2020 15:03:55
	System	11 Dec 2020 15:03:55



US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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: '2020-12-11T09:03:48', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'fdcf62e-ef74-4258-adf0-c15c6e33b228' User entered 'No (N)'	System	11 Dec 2020 15:03:55
	System	11 Dec 2020 15:03:55

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2020-12-11T09:03:53', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'fdcf62e-cf74-4258-adf0-c15c6e33b228' User entered '11 Dec 2020 09:03:53'	System	11 Dec 2020 15:03:55
	System	11 Dec 2020 15:03:55

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2020-12-18T08:29:29', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8bf318a8-f408-404a-a906-f96fe1e413de' User entered 'No (N)'	System	18 Dec 2020 14:29:39
	System	18 Dec 2020 14:29:39

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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: '2020-12-18T08:29:31', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8bf318a8-f408-404a-a906-f96fe1e413de' User entered 'No (N)'	System	18 Dec 2020 14:29:39
	System	18 Dec 2020 14:29:39

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2020-12-18T08:29:36', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8bf318a8-f408-404a-a906-f96fe1e413de' User entered '18 Dec 2020 08:29:36'	System	18 Dec 2020 14:29:39
	System	18 Dec 2020 14:29:39



**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2020-12-27T12:00:43', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '7116feb8-5965-41fa-8e0c-9c8f1406f808' User entered 'No (N)'	System	27 Dec 2020 18:00:54

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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: '2020-12-27T12:00:45', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '7116feb8-5965-41fa-8e0c-9c8f1406f808' User entered 'No (N)'	System	27 Dec 2020 18:00:54

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2020-12-27T12:00:49', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '7116feb8-5965-41fa-8e0c-9c8f1406f808' User entered '27 Dec 2020 12:00:49'	System	27 Dec 2020 18:00:54
	System	27 Dec 2020 18:00:54

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-01-05T11:59:33', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6c186f78-3be8-4498-a586-01080e76b3f2' User entered 'No (N)'	System	05 Jan 2021 17:59:45
	System	05 Jan 2021 17:59:45

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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: '2021-01-05T11:59:36', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6c186f78-3be8-4498-a586-01080e76b3f2' User entered 'No (N)'	System	05 Jan 2021 17:59:45

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-01-05T11:59:40', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6c186f78-3be8-4498-a586-01080e76b3f2' User entered '05 Jan 2021 11:59:40'	System	05 Jan 2021 17:59:45

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-01-10T12:01:10', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8ce29b87-4817-49d4-86ef-bc0dcc864df6' User entered 'No (N)'	System	10 Jan 2021 18:01:41



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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: '2021-01-10T12:01:17', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8ce29b87-4817-49d4-86ef-bc0dcc864df6' User entered 'No (N)'	System	10 Jan 2021 18:01:41

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-01-10T12:01:22', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '8ce29b87-4817-49d4-86ef-bc0dcc864df6' User entered '10 Jan 2021 12:01:22'	System	10 Jan 2021 18:01:41
	System	10 Jan 2021 18:01:41

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-01-17T12:28:45', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '3e13a889-c79a-4d77-a63f-80694cb11b1e' User entered 'No (N)'	System	17 Jan 2021 18:28:56
	System	17 Jan 2021 18:28:56

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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: '2021-01-17T12:28:47', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '3e13a889-c79a-4d77-a63f-80694cb11b1e' User entered 'No (N)'	System	17 Jan 2021 18:28:56
	System	17 Jan 2021 18:28:56

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-01-17T12:28:53', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '3e13a889-c79a-4d77-a63f-80694cb11b1e' User entered '17 Jan 2021 12:28:53'	System	17 Jan 2021 18:28:56
	System	17 Jan 2021 18:28:56



**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-01-22T08:04:52', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '01fe973d-1810-49be-96c3-6919c2b1f28e' User entered 'No (N)'	System	22 Jan 2021 14:05:02

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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: '2021-01-22T08:04:53', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '01fe973d-1810-49be-96c3-6919c2b1f28e' User entered 'No (N)'	System	22 Jan 2021 14:05:02

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-01-22T08:04:58', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '01fe973d-1810-49be-96c3-6919c2b1f28e' User entered '22 Jan 2021 08:04:58'	System	22 Jan 2021 14:05:02

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-01-29T12:21:04', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '591281c7-61a1-412c-9a29-cba9379fb278' User entered 'No (N)'	System	29 Jan 2021 18:21:18
	System	29 Jan 2021 18:21:18

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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: '2021-01-29T12:21:08', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '591281c7-61a1-412c-9a29-cba9379fb278' User entered 'No (N)'	System	29 Jan 2021 18:21:18
	System	29 Jan 2021 18:21:18

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-01-29T12:21:15', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '591281c7-61a1-412c-9a29-cba9379fb278' User entered '29 Jan 2021 12:21:15'	System	29 Jan 2021 18:21:18
	System	29 Jan 2021 18:21:18

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-02-05T12:28:24', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '42ea6041-5895-4653-803e-df59da9cdf10' User entered 'No (N)'	System	05 Feb 2021 17:28:37
	System	05 Feb 2021 17:28:37



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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: '2021-02-05T12:28:26', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '42ea6041-5895-4653-803e-df59da9cdf10'	System	05 Feb 2021 17:28:37
User entered 'No (N)'	System	05 Feb 2021 17:28:37

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-02-05T12:28:32', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '42ea6041-5895-4653-803e-df59da9cdf10' User entered '05 Feb 2021 12:28:32'	System	05 Feb 2021 17:28:37
	System	05 Feb 2021 17:28:37

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-02-12T09:22:30', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'd3ea3971-3e5a-41fb-bfa3-6531750eeb4d' User entered 'No (N)'	System	12 Feb 2021 14:22:42
	System	12 Feb 2021 14:22:42

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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: '2021-02-12T09:22:32', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'd3ea3971-3e5a-41fb-bfa3-6531750eeb4d' User entered 'No (N)'	System	12 Feb 2021 14:22:42

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-02-12T09:22:38', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'd3ea3971-3e5a-41fb-bfa3-6531750eeb4d' User entered '12 Feb 2021 09:22:38'	System	12 Feb 2021 14:22:42
	System	12 Feb 2021 14:22:42



**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-02-19T09:11:55', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '26671d4d-7737-41d1-88be-568c1da9625c' User entered 'No (N)'	System	19 Feb 2021 14:12:15
	System	19 Feb 2021 14:12:15

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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: '2021-02-19T09:12:03', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '26671d4d-7737-41d1-88be-568c1da9625c' User entered 'No (N)'	System	19 Feb 2021 14:12:15

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-02-19T09:12:11', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '26671d4d-7737-41d1-88be-568c1da9625c' User entered '19 Feb 2021 09:12:11'	System	19 Feb 2021 14:12:15
	System	19 Feb 2021 14:12:15

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-02-26T08:16:15-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '1a1d38c8-bfd0-4446-8de1-ee0c92cdad92' User entered 'No (N)'	System	26 Feb 2021 13:16:28
	System	26 Feb 2021 13:16:28

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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: '2021-02-26T08:16:16-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '1a1d38c8-bfd0-4446-8de1-ee0c92cdad92' User entered 'No (N)'	System	26 Feb 2021 13:16:28

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-02-26T08:16:23-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '1a1d38c8-bfd0-4446-8de1-ee0c92cdad92' User entered '26 Feb 2021 13:16:23'	System	26 Feb 2021 13:16:28
	System	26 Feb 2021 13:16:28

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-03-05T09:24:44-06:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '0f88e96a-97a7-4115-a113-babf1b240073' User entered 'No (N)'	System	05 Mar 2021 15:24:53



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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: '2021-03-05T09:24:38-06:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '0f88e96a-97a7-4115-a113-babf1b240073'	System	05 Mar 2021 15:24:53
User entered 'No (N)'	System	05 Mar 2021 15:24:53

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-03-05T09:24:48-06:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '0f88e96a-97a7-4115-a113-babf1b240073' User entered '05 Mar 2021 09:24:48'	System	05 Mar 2021 15:24:53
	System	05 Mar 2021 15:24:53

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: '2021-03-12T07:27:06-06:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'f376fa97-bee1-4479-b1ee-5d1e40410913'	System	12 Mar 2021 13:27:14
User entered 'No (N)'	System	12 Mar 2021 13:27:14

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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: '2021-03-12T07:27:08-06:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'f376fa97-bee1-4479-b1ee-5d1e40410913'	System	12 Mar 2021 13:27:14
User entered 'No (N)'	System	12 Mar 2021 13:27:14

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: '2021-03-12T07:27:11-06:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'f376fa97-bee1-4479-b1ee-5d1e40410913' User entered '12 Mar 2021 07:27:11'	System	12 Mar 2021 13:27:14
	System	12 Mar 2021 13:27:14



**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-03-22T15:27:29-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '5f2e25e2-967e-462b-98ca-f5b91e1d1b62' User entered 'No (N)'	System	25 Mar 2021 23:28:02
	System	25 Mar 2021 23:28:02

US3552444

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:28

Have you been exposed to someone with 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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-03-22T15:27:31-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '5f2e25e2-967e-462b-98ca-f5b91e1d1b62'	System	25 Mar 2021 23:28:02
User entered 'No (N)'	System	25 Mar 2021 23:28:02

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-03-22T15:27:35-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '5f2e25e2-967e-462b-98ca-f5b91e1d1b62'	System	25 Mar 2021 23:28:02
User entered '22 Mar 2021 15:27:35'	System	25 Mar 2021 23:28:02

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-03-26T08:05:39-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6637d168-abc9-473e-915b-49a4861c17d5'	System	26 Mar 2021 13:05:50
User entered 'No (N)'	System	26 Mar 2021 13:05:50

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-03-26T08:05:40-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6637d168-abc9-473e-915b-49a4861c17d5'	System	26 Mar 2021 13:05:50
User entered 'No (N)'	System	26 Mar 2021 13:05:50

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-03-26T08:05:46-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '6637d168-abc9-473e-915b-49a4861c17d5'	System	26 Mar 2021 13:05:50
User entered '26 Mar 2021 08:05:46'	System	26 Mar 2021 13:05:50

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-02T07:59:08-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a958c9c3-ae3f-4b0f-8391-fcc47870197b' User entered 'No (N)'	System	09 Apr 2021 15:52:40
	System	09 Apr 2021 15:52:40



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-02T07:59:11-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a958c9c3-ae3f-4b0f-8391-fcc47870197b'	System	09 Apr 2021 15:52:40
User entered 'No (N)'	System	09 Apr 2021 15:52:40

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-02T07:59:15-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a958c9c3-ae3f-4b0f-8391-fcc47870197b'	System	09 Apr 2021 15:52:40
User entered '02 Apr 2021 07:59:15'	System	09 Apr 2021 15:52:40

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-09T10:52:36-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '63fb0b08-517e-4f57-9b5b-3d66aa6eb43a' User entered 'No (N)'	System	14 Apr 2021 17:52:37

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-09T10:52:42-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '63fb0b08-517e-4f57-9b5b-3d66aa6eb43a' User entered 'No (N)'	System	14 Apr 2021 17:52:37

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-09T10:52:45-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '63fb0b08-517e-4f57-9b5b-3d66aa6eb43a' User entered '09 Apr 2021 10:52:45'	System	14 Apr 2021 17:52:37
	System	14 Apr 2021 17:52:37



**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-16T07:59:51-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'f3766036-98ff-4255-adf1-e147dbf989f4' User entered 'No (N)'	System	16 Apr 2021 13:00:07
	System	16 Apr 2021 13:00:07

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-16T07:59:54-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'f3766036-98ff-4255-adf1-e147dbf989f4'	System	16 Apr 2021 13:00:07
User entered 'No (N)'	System	16 Apr 2021 13:00:07

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-16T07:59:57-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'f3766036-98ff-4255-adf1-e147dbf989f4'	System	16 Apr 2021 13:00:07
User entered '16 Apr 2021 07:59:57'	System	16 Apr 2021 13:00:07

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-23T10:06:28-04:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a1df810f-7a18-4417-976e-c2745d13e029'	System	23 Apr 2021 14:06:47
User entered 'No (N)'	System	23 Apr 2021 14:06:47

US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-23T10:06:22-04:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a1df810f-7a18-4417-976e-c2745d13e029'	System	23 Apr 2021 14:06:47
User entered 'No (N)'	System	23 Apr 2021 14:06:47

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-04-23T10:06:43-04:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'a1df810f-7a18-4417-976e-c2745d13e029'	System	23 Apr 2021 14:06:47
User entered '23 Apr 2021 10:06:43'	System	23 Apr 2021 14:06:47

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-05-01T15:53:55-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'b5c930ca-80fb-47a5-9c9d-efab834de562'	System	01 May 2021 20:54:02
User entered 'No (N)'	System	01 May 2021 20:54:02



US3552444

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

Have you been exposed to someone with 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 (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-05-01T15:53:49-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'b5c930ca-80fb-47a5-9c9d-efab834de562'	System	01 May 2021 20:54:02
User entered 'No (N)'	System	01 May 2021 20:54:02

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D29AE164-0131-4925-8091-391E7535568A)', Time: '2021-05-01T15:53:59-05:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: 'b5c930ca-80fb-47a5-9c9d-efab834de562'	System	01 May 2021 20:54:02
User entered '01 May 2021 15:53:59'	System	01 May 2021 20:54:02

**US3552444**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

**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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:54:28**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2021-03-05T09:24:56-06:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '154d7886-67ab-4c95-9114-f2b5d4f62816'	System	05 Mar 2021 15:25:09
User entered 'No (N)'	System	05 Mar 2021 15:25:09



US3552444

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:54:28**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5157ED0E-8518-4AB1-A08A-D8FC9E58DDE8)', Time: '2021-03-05T09:25:03-06:00', User OID: 'PatientReportedOutcome (US3552444)', ODM File OID: '154d7886-67ab-4c95-9114-f2b5d4f62816' User entered '05 Mar 2021 09:25:03'	System	05 Mar 2021 15:25:09
	System	05 Mar 2021 15:25:09

US3552444

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	14 Dec 2020 18:01:39

US3552444

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '11 Dec 2020'	Heather Douds (b) (4) (b) (4)	14 Dec 2020 18:01:39

US3552444

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Contact Not Made (CONTACT NOT MADE)'	Heather Douds (b) (4) (b) (4)	14 Dec 2020 18:01:39

US3552444

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Attempted multiple calls between 12/9 and 12/11, subject did not return calls or answer.'	Heather Douds (b) (4) (b) (4)	14 Dec 2020 18:01:39

US3552444

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 21:53:13

US3552444

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:25:59
User entered 'l'	System	11 Feb 2021 21:53:13

US3552444

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:12



US3552444

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '11 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:12

US3552444

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Contact Not Made (CONTACT NOT MADE)'	Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:12

US3552444

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'didn't return any of the 10 messages left over multiple days.'	(b) (4) Stanley Dublin (b) (4)	12 Feb 2021 15:07:12

US3552444

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:17

US3552444

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered 'l'	System	12 Feb 2021 15:07:17

US3552444

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:37

US3552444

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '12 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:37

US3552444

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:37



US3552444

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:37

US3552444

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Feb 2021 15:07:41

US3552444

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered 'l'	System	12 Feb 2021 15:07:41

US3552444

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:41:59
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Mar 2021 12:22:18

US3552444

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:41:59
User entered '15 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Mar 2021 12:22:18

US3552444

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:41:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Mar 2021 12:22:18

US3552444

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:41:59
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Mar 2021 12:22:18

US3552444

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:41:59
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Mar 2021 12:22:22



US3552444

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered 'l'	System	16 Mar 2021 12:22:22

US3552444

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:17

US3552444

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered '31 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:17

US3552444

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:17

US3552444

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered 'VISIT4'	System	31 Mar 2021 15:12:17

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20



US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered empty.	System	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered empty.	System	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered empty.	System	31 Mar 2021 15:12:20



US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered empty.	System	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered empty.	System	31 Mar 2021 15:12:20

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57

US3552444

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57

US3552444

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:24

US3552444

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:12:24



US3552444

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:14:05

US3552444

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered '31 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:14:05

US3552444

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered '09:31'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:14:05

US3552444

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered '31 Mar 2021 09:31'	System	31 Mar 2021 15:14:05

US3552444

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 15:14:09

US3552444

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:04:57
User entered 'l'	System	31 Mar 2021 15:14:09

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:53:21

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:53:21



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:53:21

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 16:53:21

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:41:59
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:33:39

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:41:59
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:33:39

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:53:41



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Not Administered (NA)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'I'	System	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:28

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'I'	System	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered empty.	System	25 Jan 2021 16:54:25
DataPoint set to visible.	System	25 Jan 2021 16:53:41



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered empty.	System	25 Jan 2021 16:54:25
DataPoint set to visible.	System	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '09:14'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered '25 Jan 2021 09:14'	System	25 Jan 2021 16:54:25



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '98.7' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '67'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'bpm'	System	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '16'	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'breaths/min'	System	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '130'	(b) (4) Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:54:25



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mmHg'	System	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '66'	Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mmHg'	System	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:25

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered empty.	System	25 Jan 2021 16:54:25
DataPoint set to visible.	System	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '10:05'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered '25 Jan 2021 10:05'	System	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '97.1' F	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '62'	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'bpm'	System	25 Jan 2021 16:54:51



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'breaths/min'	System	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '119'	(b) (4) Stanley Doublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mmHg'	System	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 06:53:11
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 17:54:04
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Jan 2021 16:54:51
User entered '53'	Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mmHg'	System	25 Jan 2021 16:54:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:55:51

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:55:51



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 16:56:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 16:56:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	25 Jan 2021 16:56:09
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:56:03
User entered empty.	Stanley Doublin (b) (4)	25 Jan 2021 16:56:03

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:03

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:03

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mRNA-1273'	System	25 Jan 2021 16:56:09
User entered empty.	System	25 Jan 2021 16:56:03
DataPoint set to visible.	System	25 Jan 2021 16:53:41

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:03

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '09:35'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:03

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered '25 Jan 2021 09:35'	System	25 Jan 2021 16:56:03

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:03



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'ONCE'	System	25 Jan 2021 16:56:09
User entered empty.	System	25 Jan 2021 16:56:03

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 16:56:09
User entered empty.	System	25 Jan 2021 16:56:03

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	25 Jan 2021 16:56:19

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:19

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '08:05'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:19

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered '25 Jan 2021 08:05'	System	25 Jan 2021 16:56:19

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:27

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:27



US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '08:11'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 16:56:27

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered '25 Jan 2021 08:11'	System	25 Jan 2021 16:56:27

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	05 Feb 2021 16:54:31

US3552444

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'I'	System	05 Feb 2021 16:54:31

US3552444

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	05 Feb 2021 16:54:57

US3552444

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '1 Feb 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Feb 2021 16:54:57

US3552444

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Contact Not Made (CONTACT NOT MADE)'	Heather Douds (b) (4) (b) (4)	05 Feb 2021 16:54:57

US3552444

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Subject did not answer or return calls in spite of multiple attempts'	Heather Douds (b) (4) (b) (4)	05 Feb 2021 16:54:57



US3552444

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 21:53:20

US3552444

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'l'	System	11 Feb 2021 21:53:20

US3552444

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'I'	System	11 Feb 2021 21:53:20
DataPoint set to visible.	System	11 Feb 2021 21:53:20

US3552444

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:16

US3552444

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '5 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:16

US3552444

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:16

US3552444

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'OLD29'	System	05 Mar 2021 18:28:16

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	05 Mar 2021 18:28:35



US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '5 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '10:30'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered '5 Mar 2021 10:30'	System	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '98' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '61'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35



US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'bpm'	System	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'breaths/min'	System	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '134'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mmHg'	System	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '65'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mmHg'	System	05 Mar 2021 18:28:35

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	05 Mar 2021 18:28:57



US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '5 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '11:31'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered '5 Mar 2021 11:31'	System	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '98.3' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '58'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57



US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'bpm'	System	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '15'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'breaths/min'	System	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '128'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mmHg'	System	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '63'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mmHg'	System	05 Mar 2021 18:28:57

US3552444

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:29:13



US3552444

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '5 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:29:13

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:36:39

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:36:39

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:36:39

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'mRNA-1273'	System	05 Mar 2021 18:36:39
DataPoint set to visible.	System	11 Feb 2021 21:53:20

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '5 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:36:39

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered '11:01'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:36:39

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered '5 Mar 2021 11:01'	System	05 Mar 2021 18:36:39



US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:36:39

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'ONCE'	System	05 Mar 2021 18:36:39

US3552444

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 18:36:39

US3552444

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:04:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 18:36:44

US3552444

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'l'	System	05 Mar 2021 18:36:44

US3552444

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:41:59
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	16 Mar 2021 14:42:13

US3552444

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:41:59
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 04:52:06
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'appropriately within window' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	16 Mar 2021 14:42:37
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Mar 2021 14:42:13
User entered '11 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	16 Mar 2021 14:42:13

US3552444

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:41:59
User entered 'Contact Not Made (CONTACT NOT MADE)'	Cassandra Zehenny (b) (4) (b) (4)	16 Mar 2021 14:42:13



US3552444

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:41:59
User entered 'attempted multiple calls and left three voicemails but never received return call'	Cassandra Zehenny (b) (4) (b) (4)	16 Mar 2021 14:42:13

US3552444

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:41:59
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	16 Mar 2021 14:43:18

US3552444

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:21
User entered 'l'	System	16 Mar 2021 14:43:18

US3552444

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:24

US3552444

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered '31 Mar 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:24

US3552444

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:24

**US3552444**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:54:28**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 15:14:24

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28



US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

**US3552444**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:54:28**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:14:28



US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:14:28

US3552444

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:32

US3552444

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:32



US3552444

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:40

US3552444

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered '31 Mar 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:40

US3552444

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:55
User entered '09:31'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 15:14:40

**US3552444**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 09:31'	System	31 Mar 2021 15:14:40

US3552444

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:54:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:31:57

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56



US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '11 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[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: 11 Aug 2021 22:54:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '12 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[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: 11 Aug 2021 22:54:28

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56



US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'None (NONE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56



US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:33:56

US3552444

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:28

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: 11 Aug 2021 22:54:28

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: 11 Aug 2021 22:54:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54



US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered '01 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:04:38
User entered '1 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User entered empty.	System	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	28 Oct 2020 15:42:21
User entered 'Yes (Y)'	(b) (4)	
	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44
	(b) (4)	



US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	28 Oct 2020 15:42:21
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44
	(b) (4)	

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User entered empty.	System	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44



US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44



US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Stanley Dublin (b) (4)	28 Oct 2020 15:42:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Mikayla Frye (b) (4)	15 Oct 2020 14:34:44
	(b) (4)	

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 14:34:44



US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User entered '0'	System	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54
User entered 'l'	System	15 Oct 2020 14:34:44

US3552444

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:55:54

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:54:28**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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 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: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'seasonal allergies'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '10' reason for change: Per Query Resolution	(b) (4) Cassandra Zehenny (b) (4)	03 Nov 2020 15:46:00
User entered '1'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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) (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) (b) (4)	03 Nov 2020 15:46:12
User entered 'mg (mg)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (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) (b) (4)	17 Sep 2020 13:43:39

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:54:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2000'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Sep 2020 13:43:39

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'asthma'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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 'I'	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: 11 Aug 2021 22:54:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Other (OTHER)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'puff'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	17 Sep 2020 15:11:04
User entered 'un UNK 1990' reason for change: Data Entry Error	Stanley Doublin (b) (4) (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 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Sep 2020 13:47:16

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 13:47:16

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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 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: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'benign prostatic hypertrophy'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '8'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2000'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) 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 Doublin (b) (4) (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) (b) (4)	17 Sep 2020 13:49:16

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) 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) (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) (b) (4)	17 Sep 2020 13:49:16

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

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



US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

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

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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: 11 Aug 2021 22:54:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'atrial fibrillation'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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)	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 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: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	15 Oct 2020 12:35:34
User entered 'Yes (Y)'	(b) (4)	
	Stanley Dublin (b) (4)	17 Sep 2020 13:50:02
	(b) (4)	

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '11 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	15 Oct 2020 12:35:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	17 Sep 2020 13:50:02
	(b) (4)	



US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User entered 'I'	System	17 Sep 2020 13:50:02

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
User entered 'I'	System	17 Sep 2020 13:50:02

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:54:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:35
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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'benign prostatic hypertrophy'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '5'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty; reason for change Data Entry Error	(b) (4) Cassandra Zehenny (b) (4)	21 Oct 2020 14:51:22
User entered 'every other day'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2000'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) Coder Import (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)	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: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'hypercholesterolemia'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '20'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2010'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Sep 2020 13:53:54

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Sep 2020 13:53:54

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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 Doublin (b) (4)	17 Sep 2020 13:54:54

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'gastroesophageal reflux disease'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '40'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2000'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

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



US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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: 11 Aug 2021 22:54:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'hypertension'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '10'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'twice daily (BID)'	(b) (4) 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: 11 Aug 2021 22:54:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2018'	(b) (4) 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: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	28 Oct 2020 15:48:30
User entered 'Yes (Y)'	(b) (4)	
	Stanley Dublin (b) (4)	17 Sep 2020 13:55:38
	(b) (4)	

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
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: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
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: 11 Aug 2021 22:54:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:16:55
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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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 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: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'benign prostatic hypertrophy'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '5'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2018'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Sep 2020 13:56:27

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 13:56:27

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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: 11 Aug 2021 22:54:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '10'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2019'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Sep 2020 13:57:05

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 13:57:05

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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 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: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4) Cassandra Zehenny (b) (4)	03 Nov 2020 15:50:41
User entered 'No (N)'	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: 11 Aug 2021 22:54:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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) (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 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '5'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'twice daily (BID)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'un UNK 2019'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 13:57:54

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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: CEFALLEXIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (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 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: 11 Aug 2021 22:54:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'tooth extraction'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '500'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'twice daily (BID)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '13 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 12:39:49

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) 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: 11 Aug 2021 22:54:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'tooth extraction'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '325'	(b) (4) 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: 11 Aug 2021 22:54:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	15 Oct 2020 12:40:27

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once (ONCE)'	(b) (4) 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: 11 Aug 2021 22:54:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '13 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '13 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:54:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
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: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
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: 11 Aug 2021 22:54:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:12
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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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.	(b) (4) Coder Import (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)	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)	15 Oct 2020 12:41:01

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:54:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'atrial fibrillation'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '25'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'twice daily (BID)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:54:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '12 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 12:41:01

US3552444

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:54:28**

[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: 11 Aug 2021 22:54:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
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)	12 Feb 2021 15:09:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 15:09:49
Data point term sent to Coder	System	12 Feb 2021 15:09:23
Coding entries removed.	Stanley Dublin (b) (4)	12 Feb 2021 15:09:00
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 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: 11 Aug 2021 22:54:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:54:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'influenza PROPHYLAXIS' reason for change: Data Entry Error	(b) (4)	12 Feb 2021 15:09:00
User entered 'prophylaxis'	Stanley Dublin (b) (4)	28 Oct 2020 15:44:13
	(b) (4)	

US3552444

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:54:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of vaccine/Injection 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)	22 Jan 2021 03:29:05
Query 'Per DM CLR: Please provide the actual dose for this medication instead of vaccine/Injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with ' Subject reported data, exact dosage unknown. Thank you. ' (Site from DM).	Cassandra Zehenny (b) (4)	19 Jan 2021 19:31:45
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of vaccine/Injection 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)	19 Jan 2021 04:42:36
User entered 'I'	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: 11 Aug 2021 22:54:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Other (OTHER)'	(b) (4) 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: 11 Aug 2021 22:54:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'injection'	(b) (4) 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: 11 Aug 2021 22:54:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'once (ONCE)'	(b) (4) 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: 11 Aug 2021 22:54:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) 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: 11 Aug 2021 22:54:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '21 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:54:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '0'	(b) (4) 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: 11 Aug 2021 22:54:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '21 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:54:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
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: 11 Aug 2021 22:54:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
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: 11 Aug 2021 22:54:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:17:24
User entered empty.	System	28 Oct 2020 15:44:13

US3552444

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:54:28**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:24:12

US3552444

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 22:54:28**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '13 Oct 2020'	(b) (4) Cassandra Zehenny (b) (4)	02 Nov 2020 17:25:01

US3552444

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 22:54:28**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Tooth Extraction'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:25:01

US3552444

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 22:54:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered 'Medical History (MH)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:25:01

US3552444

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 22:54:28**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 17:25:01

US3552444

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:28

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:21:47
User entered '14 Oct 2020'	(b) (4) Joan Siegner (b) (4)	15 Oct 2020 13:23:36



US3552444

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:28

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:21:47
User entered 'AE (specify) (ADVERSE EVENT)'	Joan Siegner (b) (4) [REDACTED]	15 Oct 2020 13:23:36

US3552444

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:28

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:21
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 19:21:47
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4)	
User closed query 'Please update to AE#3 ( actual line item for this AE) ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 23:32:41
Query 'Please update to AE#3 ( actual line item for this AE) ' answered with 'updated' (Site from CRA).		19 Nov 2020 19:53:58
User entered 'AE #3' reason for change: Per Query Resolution	Heather Douds (b) (4)	19 Nov 2020 19:37:48
User opened query 'Please update to AE#3 ( actual line item for this AE) ' (Site from CRA).	(b) (4)	
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Heather Douds (b) (4)	19 Nov 2020 19:37:43
User entered 'AE #2' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:47:57
Query 'Please check spelling ' canceled (Site from CRA).	Cassandra Zehenny (b) (4)	18 Nov 2020 17:46:22
User opened query 'Please check spelling ' (Site from CRA).	(b) (4)	
User entered 'worsening of arrhythmia'	Cassandra Zehenny (b) (4)	18 Nov 2020 17:46:18
	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:18:15
		20 Oct 2020 15:44:37
		20 Oct 2020 15:43:36
	Joan Siegner (b) (4)	15 Oct 2020 13:23:36