

US3552473 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:17:31

All time stamps listed in this document are displayed in GMT

US3552473

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Participant ID

US3552473

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

US3552473

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
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	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 19:30:21

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Date of Informed Consent (<i>dd MMM yyyy</i>)	19 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 checked="" type="radio"/> No <input type="radio"/>
If Yes, previous participant number	US3552381
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 19:30:21

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 19:30:21

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Condition	HUMAN IMMUNODIFICIENCY VIRUS
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	MAJOR CLINICAL DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	INDOOR ALLERGIES
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)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	ALLERGY TO CODEINE
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	HEPATITIS C
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	ELEVATED LIVER ENZYMES
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)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	PULMONARY EMBOLUS
Start date (dd MMM yyyy)	UN NOV 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 NOV 2018
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	NOV 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	BILATERAL MASTOIDITIS
Start date (dd MMM yyyy)	UN NOV 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 NOV 2018
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	NOV 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	BILATERAL PERIORBITAL CELLUTLITIS
Start date (dd MMM yyyy)	UN JAN 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	GONORRHEA
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)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Condition	SYPHILLIS
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)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 SEP 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 09:10
Height (xxx.x)	74 in
Weight (xxx.x)	204.6 lb
BMI (xxx.x)	26.32401 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:30:21

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:30:21

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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 ☐

Specify

(b) (6) IN GROCERY
STORE COUPLE TIMES/WEEK;
GROCERY/RETAIL TWICE
WKLY, TAKES PUBLIC
TRANSPORTATION

Location and Living Circumstances Risk (check all that apply)

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:30:21

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No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	1 NIECE IN KINDERGARTEN 5 DAYS/WK; VISITS 3 TIMES/WK.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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

What was the participant's randomization number? 146288

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☒ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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)	19 SEP 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 09:10
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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)	19 SEP 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 10:54
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 19 SEP 2020

What was the treatment time? (00:00-23:59) 10:24 (24 HR)

Treatment Date and Time (derived) 19 SEP 2020 10:24

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 SEP 2020
Collection time (00:00-23:59)	09:40 (24 HR)
Collection date and time (derived)	19 SEP 2020 09:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)			19 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:48	19 SEP 2020 09:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 10:54

PC Open Date & Time

19 SEP 2020 10:44

PC Close Date & Time

19 SEP 2020 13:14

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 97.9 °F

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

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

PC Time Stamp	20 SEP 2020 09:49
PC Open Date & Time	19 SEP 2020 14:09
PC Close Date & Time	20 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

22 SEP 2020 12:18

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

23 SEP 2020 12:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

24 SEP 2020 14:22

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 12:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 10:55

PC Open Date & Time

19 SEP 2020 10:44

PC Close Date & Time

19 SEP 2020 13:14

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

20 SEP 2020 09:49

PC Open Date & Time

19 SEP 2020 14:09

PC Close Date & Time

20 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 12:01

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:18

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 12:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 14:23

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 12:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 10:55
PC Open Date & Time	19 SEP 2020 10:44
PC Close Date & Time	19 SEP 2020 13:14

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

No ☒

Yes ☐

PC Time stamp	20 SEP 2020 09:50
PC Open Date & Time	19 SEP 2020 14:09
PC Close Date & Time	20 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 ☒

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

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US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:19
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

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EAB) (1725)

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:07
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

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EAB) (1725)

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 14:23
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

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)

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US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3552473

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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)	09:25 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 09:25
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 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)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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)	14 OCT 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 11:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3552473

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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) 14 OCT 2020

What was the treatment time? (00:00-23:59) 10:26 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 10:26

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

US3552473

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	10:00 (24 HR)
Collection date and time (derived)	14 OCT 2020 10:00

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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	10:01	14 OCT 2020 10:01
Nasopharyngeal Swab 2	No		

US3552473

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 10:50

PC Open Date & Time

14 OCT 2020 10:46

PC Close Date & Time

14 OCT 2020 13:16

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	14 OCT 2020 15:36
PC Open Date & Time	14 OCT 2020 14:11
PC Close Date & Time	15 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 12:07

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

99.3 °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

16 OCT 2020 13:11

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 15:06

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 12:02

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 12:31

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 15:10

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

14 OCT 2020 10:51

PC Open Date & Time

14 OCT 2020 10:46

PC Close Date & Time

14 OCT 2020 13:16

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

14 OCT 2020 15:36

PC Open Date & Time

14 OCT 2020 14:11

PC Close Date & Time

15 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

15 OCT 2020 12:07

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

16 OCT 2020 13:12

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

17 OCT 2020 15:06

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

18 OCT 2020 12:03

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

19 OCT 2020 12:31

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

20 OCT 2020 15:11

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 10:51
PC Open Date & Time	14 OCT 2020 10:46
PC Close Date & Time	14 OCT 2020 13:16

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 15:35
PC Open Date & Time	14 OCT 2020 14:11
PC Close Date & Time	15 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

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US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 12:08
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 13:12
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 ☒

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 15:08
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 12:03
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 12:32
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

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)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 15:11
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3552473

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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

US3552473

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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

US3552473

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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) _____

US3552473

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

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.

US3552473

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 NOV 2020
Collection time (00:00-23:59)	09:14 (24 HR)
Collection date and time (derived)	09 NOV 2020 09:14

US3552473

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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°F/38°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"/>

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 NOV 2020 10:52:06
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 DEC 2020 13:23:31
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 DEC 2020 05:14:31
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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	14 DEC 2020 07:59:32
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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	21 DEC 2020 08:15:00
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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	04 JAN 2021 08:31:35
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

11 JAN 2021 18:05:00

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 18:37:50
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

25 JAN 2021 18:45:12

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

01 FEB 2021 15:37:37

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

08 FEB 2021 05:32:53

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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	15 FEB 2021 05:23:31
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	22 FEB 2021 07:16:07
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

01 MAR 2021 02:06:46

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

08 MAR 2021 03:29:52

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 MAR 2021 07:00:59
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 MAR 2021 08:48:18
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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	29 MAR 2021 00:51:01
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 APR 2021 07:46:36
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

12 APR 2021 18:57:58

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

19 APR 2021 07:08:26

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	28 APR 2021 08:36:50
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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="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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JAN 2022 00:01

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04 FEB 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 MAR 2022 00:01

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11 MAR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 APR 2022 00:01

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22 APR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

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06 MAY 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

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13 MAY 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

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20 MAY 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

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27 MAY 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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03 JUN 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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10 JUN 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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17 JUN 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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24 JUN 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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27 JUN 2022 00:01

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01 JUL 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 AUG 2022 00:01

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05 AUG 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 AUG 2022 00:01

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19 AUG 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 AUG 2022 00:01

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26 AUG 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 AUG 2022 00:01

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02 SEP 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

[Patient Cloud Open Date & Time](#)

14 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2022 23:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2022 23:59

US3552473

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:17:31

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		28 FEB 2021 13:13:01

US3552473

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:43:28

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:43:28

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

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) _____

US3552473

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

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.

US3552473

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	13:08 (24 HR)
Collection date and time (derived)	29 MAR 2021 13:08

US3552473

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

US3552473

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552473

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:17:31

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"/>

US3552473

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:17:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552473

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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

Visit date (dd MMM yyyy)	21 JAN 2021
--------------------------	-------------

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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US3552473

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:43:28

Generated On: 10 Jun 2021 08:17:31

Date of updated informed consent (<i>dd MMM yyyy</i>)	21 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 (<i>dd MMM yyyy</i>)	21 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 checked="" type="radio"/> Not Administered <input 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

US3552473

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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

US3552473

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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)	21 JAN 2021
Time of assessment (00:00-23:59)	08:33 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 08:33
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3552473

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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)	21 JAN 2021
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 11:10
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)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3552473

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3552473

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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) 21 JAN 2021

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 10:40

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

US3552473

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00-23:59)	08:24 (24 HR)
Collection date and time (derived)	21 JAN 2021 08:24

US3552473

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	08:28
Collection Date and Time (derived)	21 JAN 2021 08:28

US3552473

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments NEVER RETURNED ANY CALLS/MESSAGES WE LEFT.

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:21

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3552473

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 FEB 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

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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)	18 FEB 2021
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 13:50
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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)	18 FEB 2021
Time of assessment (00:00-23:59)	14:28 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 14:28
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3552473

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3552473

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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) 18 FEB 2021

What was the treatment time? (00:00-23:59) 13:58 (24 HR)

Treatment Date and Time (derived) 18 FEB 2021 13:58

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

US3552473

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:31:53

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552473

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:31:53

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552473

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

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) _____

US3552473

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

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.

US3552473

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 16:33:41

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	13:08 (24 HR)
Collection date and time (derived)	29 MAR 2021 13:08

US3552473

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

AEID	USA-US089-2020-MRNA-1273-P30 1000015
Adverse event	PERIRECTAL ABSCESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 NOV 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)	01 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	25 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

SUBJECT REPORTED
HOSPITALIZATION FOR
PERIRECTAL ABSCESS.
ADMITTED EVENING OF 24NOV
FOR RECTAL DISCOMFORT, CT
SCAN OF ABDOMEN AND
PELVIS WITH CONTRAST
SHOWING 2.5CM PERIRECTAL
ABSCESS AND STANDARD
LABS DRAWN. TAKEN TO OR
FOR INCISION AND DRAINAGE
OF ABSCESS AND THEN
DISCHARGED BEFORE LUNCH
ON 25NOV. WHILE IN
HOSPITAL, SUBJECT RECEIVED
ONE DOSE OF UNKNOWN
AMOUNTS OF BOTH ROCEPHIN
AND ZOSYN. SENT HOME ON
ORAL ANTIBIOTICS WHICH
SUBJECT HAS SINCE
COMPLETED. SUBJECT IS
FULLY RECOVERED.

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

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

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

Yes ☒

No ☐

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

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication BIKTARVY

Prophylaxis Yes ☐
No ☒

Indication HUMAN IMMUNODEFICIENCY
VIRUS

Dose per administration 50/200/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 2017	
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"/>

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication BUPROPRION

Prophylaxis Yes ☐
No ☒

Indication MAJOR CLINICAL DEPRESSION

Dose per administration 450

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication BUSPRIONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED ACHES

Dose per administration 400

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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	1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

Dose per administration 1000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLACTIC

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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)		30 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)		30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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)	25 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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)	25 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 checked="" 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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication Tiotropium

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)		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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication VARENICLINE

Prophylaxis Yes ☒
No ☐

Indication SMOKING CESSATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 14:28:58

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	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)	14 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)	28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration UNK

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

If dose unit is Other, specify DOSE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 checked="" 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)		24 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 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"/>

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration UNK

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

If dose unit is Other, specify DOSE

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)

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US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 checked="" 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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 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"/>

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication LACTATED RINGERS
INTRAVENOUS FLUID

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 350

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)

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US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 NOV 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"/>

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

Name of Medication SYMMETREL

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 14:28:58

Generated On: 10 Jun 2021 08:17:31

	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)	25 MAR 2021	
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"/>

US3552473

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3552473

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 NOV 2020	INCISION AND DRAINAGE OF PERIRECTAL ABSCESS	Adverse Event	

US3552473

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:17:31

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3552473

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US089-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US089-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/DEC/2020 13:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US089-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/DEC/2020 10:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US089-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/DEC/2020 17:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 19:30:20

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US089-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/DEC/2020 13:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3552473 (Prod: Saint Louis University)

US3552473

Form: Participant Creation

Generated On: 10 Jun 2021 08:17:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'US3552473'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 14:54:13

US3552473

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:12

US3552473

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 14:54:14

US3552473

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:12

US3552473

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'SCRN'	System	19 Sep 2020 19:30:12

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered (b) (6) 1967'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 14:54:16

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '53'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'YEARS'	System	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '53'	System	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Male (M)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:41

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Sep 2020'	System	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2020'	System	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Sep 2020 15:02:07
User entered 'No (N)'	(b) (4), (b) (6)	19 Sep 2020 15:01:48

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Was this participant screened previously is No, however previous participant number has been provided. Please correct.' (Site from System).	(b) (4) System	19 Sep 2020 15:02:07
User opened query 'Was this participant screened previously is No, however previous participant number has been provided. Please correct.' (Site from System).	System	19 Sep 2020 15:01:48
User entered 'US3552381'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 14:54:14

US3552473

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'l'	System	19 Sep 2020 15:02:16

US3552473

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:02:16

US3552473

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:17:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:30:50

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: Human immunodeficiency virus syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	20 Sep 2020 04:37:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Sep 2020 04:37:40
Data point term sent to Coder	System	19 Sep 2020 19:31:48
User entered 'human immunodeficiency virus'	Mikayla Frye (b) (4)	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 1997'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 1997'	System	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '1997'	System	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:31:18

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Major depression, LLT: Clinical depression - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Sep 2020 04:40:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Sep 2020 04:40:41
Data point term sent to Coder	System	19 Sep 2020 19:31:49
User entered 'major clinical depression'	Mikayla Frye (b) (4)	19 Sep 2020 19:31:31
	(b) (4)	

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 1996'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 1996'	System	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '1996'	System	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:31:31

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 19:32:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 19:32:46
Data point term sent to Coder	System	19 Sep 2020 19:31:51
User entered 'anxiety'	Mikayla Frye (b) (4)	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 1996'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 1996'	System	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '1996'	System	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:31:44

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 19:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 19:33:46
Data point term sent to Coder	System	19 Sep 2020 19:32:51
User entered 'indoor allergies'	Mikayla Frye (b) (4)	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 2010'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 2010'	System	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2010'	System	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:32:00

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Sep 2020 19:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 19:33:46
Data point term sent to Coder	System	19 Sep 2020 19:32:53
User entered 'allergy to codeine'	Mikayla Frye (b) (4)	19 Sep 2020 19:32:16
	(b) (4)	

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 1985'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 1985'	System	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '1985'	System	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:32:16

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 19:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 19:33:46
Data point term sent to Coder	System	19 Sep 2020 19:32:54
User entered 'hepatitis c'	Mikayla Frye (b) (4)	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 1997'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 2010'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 1997'	System	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '1997'	System	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 2010'	System	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2010'	System	19 Sep 2020 19:32:31

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Investigations, HLT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Hepatic enzyme increased, LLT: Elevated liver enzymes - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	19 Sep 2020 19:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 19:33:46
Data point term sent to Coder	System	19 Sep 2020 19:32:53
User entered 'elevated liver enzymes'	Mikayla Frye (b) (4)	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 2010'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 2010'	System	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2010'	System	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	19 Sep 2020 19:32:46

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:11:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:11:24
Data point term sent to Coder System	System	07 Dec 2020 17:48:29
User entered 'Chronic Obstructive Pulmonary Disease'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:47:44

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolus - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:11:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:11:24
Data point term sent to Coder	System	07 Dec 2020 17:48:29
User entered 'Pulmonary embolus'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'un Nov 2018' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:50:25
User entered '27 Nov 2018'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Dec 2020 17:50:25
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Dec 2020 17:50:15
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Dec 2020 17:50:15
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Dec 2020 17:50:15
User entered 'UN Nov 2018' reason for change:	Cassandra Zehenny (b) (4)	07 Dec 2020 17:50:15
Data Entry Error	(b) (4)	
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Dec 2020 17:48:11
User entered 'un UNK 2018'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:48:11
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Nov 2018'	System	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2018'	System	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Nov 2018'	System	07 Dec 2020 17:50:15
User entered 'Jan 2018'	System	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2018'	System	07 Dec 2020 17:48:11

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Mastoiditis, LLT: Mastoiditis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:18:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:18:01
Data point term sent to Coder	System	07 Dec 2020 17:49:30
User entered 'Bilateral mastoiditis'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'un Nov 2018' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:50:44
User entered '27 Nov 2018'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Dec 2020 17:50:44
User entered 'UN Nov 2018' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:50:44
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Dec 2020 17:48:36
User entered 'un UNK 2018'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:36

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Nov 2018'	System	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2018'	System	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Nov 2018'	System	07 Dec 2020 17:50:44
User entered 'Jan 2018'	System	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2018'	System	07 Dec 2020 17:48:36

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Periorbital cellulitis, LLT: Periorbital cellulitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:18:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:18:02
Data point term sent to Coder	System	07 Dec 2020 17:49:30
User entered 'bilateral periorbital cellulitis'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'un Jan 2013' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:50:56
User entered '28 Jan 2013'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	07 Dec 2020 17:50:56
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Dec 2020 17:49:07
User entered 'un UNK 2013'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:49:07
	(b) (4)	

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 2013'	System	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2013'	System	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'Jan 2013'	System	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '2013'	System	07 Dec 2020 17:49:07

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Neisseria infections, PT: Gonorrhoea, LLT: Gonorrhea - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:11:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:11:26
Data point term sent to Coder	System	07 Dec 2020 17:49:30
User entered 'gonorrhea'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:49:23

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Treponema infections, PT: Syphilis, LLT: Syphilis - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:11:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:11:39
Data point term sent to Coder	System	07 Dec 2020 17:50:31
User entered 'syphillis'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered empty.	System	07 Dec 2020 17:49:39

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09:10'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '19 Sep 2020 09:10'	System	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '74' in	(b) (4) Mikayla Frye (b) (4)	19 Sep 2020 19:33:21
DataPoint set to visible.	(b) (4) System	19 Sep 2020 15:02:16

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '204.6' lb	(b) (4) Mikayla Frye (b) (4)	19 Sep 2020 19:33:21
DataPoint set to visible.	(b) (4) System	19 Sep 2020 15:02:16

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered '26.32401'	System	19 Sep 2020 19:33:21
DataPoint set to visible.	System	19 Sep 2020 15:02:16

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'kg/m2'	System	19 Sep 2020 19:33:21
DataPoint set to visible.	System	19 Sep 2020 15:02:16

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'bpm'	System	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'breaths/min'	System	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'mmHg'	System	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User entered 'mmHg'	System	19 Sep 2020 19:33:21

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59

US3552473

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59

US3552473

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:29

US3552473

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:33:29

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

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[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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered (b) (6) in grocery store couple times/week;	(b) (4)	
grocery/retail twice wkly, takes public transportation'	Mikayla Frye (b) (4)	19 Sep 2020 19:34:55
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered '1 niece in kindergarten 5 days/wk; visits 3 times/wk.'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:34:55

US3552473

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:35:10

US3552473

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:35:10

US3552473

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:35:10

US3552473

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'VISIT1'	System	19 Sep 2020 19:35:10

US3552473

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 15:04:09

US3552473

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '146288'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 15:04:09

US3552473

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Data correctly entered as at risk "yes" under HIV, please review' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 09:28:43
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	Heather Douds (b) (4)	01 Oct 2020 14:46:52
	(b) (4)	
	System	30 Sep 2020 22:36:51
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 09:24:44
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'HIV marked as yes' (Site from System).	Mikayla Frye (b) (4)	19 Sep 2020 19:35:40
	(b) (4)	
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	19 Sep 2020 19:35:27
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 15:04:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:35:27

US3552473

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:35:27

US3552473

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:35:27

US3552473

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:35:27

US3552473

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:35:27

US3552473

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4)	19 Sep 2020 19:35:27
DataPoint set to visible.	(b) (4) System	19 Sep 2020 15:01:48

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09:10'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered '19 Sep 2020 09:10'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '97.6' F	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (Oral)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '85'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'bpm'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '18'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'breaths/min'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '144'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'mmHg'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '87'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'mmHg'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '10:54'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered '19 Sep 2020 10:54'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '97.5' F	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (Oral)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered empty.	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '74'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'bpm'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '20'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'breaths/min'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '136'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'mmHg'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '87'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'mmHg'	System	19 Sep 2020 19:36:56

US3552473

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:00

US3552473

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:00

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'MRNA-1273 OR PLACEBO'	System	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '10:24'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered '19 Sep 2020 10:24'	System	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'ONCE'	System	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'INTRAMUSCULAR'	System	19 Sep 2020 15:26:27

US3552473

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:13

US3552473

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:13

US3552473

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09:40'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:13

US3552473

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered '19 Sep 2020 09:40'	System	19 Sep 2020 19:37:13

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '19 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09:48'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered '19 Sep 2020 09:48'	System	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered empty.	System	19 Sep 2020 19:37:25

US3552473

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	26 Sep 2020 19:08:38

US3552473

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'I'	System	26 Sep 2020 19:08:38

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:54:24', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '3e5448a3-2779-4cf7-8317-64ff0063f1a6'	System	19 Sep 2020 15:54:48
User entered 'Yes (Y)'	System	19 Sep 2020 15:54:48

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:54:31', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '3e5448a3-2779-4cf7-8317-64ff0063f1a6'	System	19 Sep 2020 15:54:48
User entered '97.5'	System	19 Sep 2020 15:54:48

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:54:34', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '3e5448a3-2779-4cf7-8317-64ff0063f1a6'	System	19 Sep 2020 15:54:48
User entered 'No (N)'	System	19 Sep 2020 15:54:48

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:54:43', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '3e5448a3-2779-4cf7-8317-64ff0063f1a6'	System	19 Sep 2020 15:54:48
User entered '19 Sep 2020 10:54'	System	19 Sep 2020 15:54:48

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 10:44'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 13:14'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:48:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'ba542a8a-bc1a-4cdc-916f-e2a71a6857fc'	System	20 Sep 2020 14:49:11
User entered 'Yes (Y)'	System	20 Sep 2020 14:49:11

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:48:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'ba542a8a-bc1a-4cdc-916f-e2a71a6857fc' User entered '97.9'	System	20 Sep 2020 14:49:11
	System	20 Sep 2020 14:49:11

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'ba542a8a-bc1a-4cdc-916f-e2a71a6857fc'	System	20 Sep 2020 14:49:11
User entered 'No (N)'	System	20 Sep 2020 14:49:11

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:07', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'ba542a8a-bc1a-4cdc-916f-e2a71a6857fc'	System	20 Sep 2020 14:49:11
User entered '20 Sep 2020 09:49'	System	20 Sep 2020 14:49:11

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 14:09'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 2'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:00:59', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '37953514-be79-495a-8ab1-1b77985ea06c'	System	20 Sep 2020 17:01:28
User entered 'Yes (Y)'	System	20 Sep 2020 17:01:28

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:09', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '37953514-be79-495a-8ab1-1b77985ea06c' User entered '97.9'	System	20 Sep 2020 17:01:28
	System	20 Sep 2020 17:01:28

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '37953514-be79-495a-8ab1-1b77985ea06c'	System	20 Sep 2020 17:01:28
User entered 'No (N)'	System	20 Sep 2020 17:01:28

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:16', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '37953514-be79-495a-8ab1-1b77985ea06c'	System	20 Sep 2020 17:01:28
User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:01:28

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 3'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:00:32', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'aa240e50-36bc-4497-a65f-270849a737ef'	System	21 Sep 2020 17:03:27
User entered 'Yes (Y)'	System	21 Sep 2020 17:03:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:00:39', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'aa240e50-36bc-4497-a65f-270849a737ef' User entered '98.1'	System	21 Sep 2020 17:03:27
	System	21 Sep 2020 17:03:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:00:42', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'aa240e50-36bc-4497-a65f-270849a737ef'	System	21 Sep 2020 17:03:27
User entered 'No (N)'	System	21 Sep 2020 17:03:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:00:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'aa240e50-36bc-4497-a65f-270849a737ef'	System	21 Sep 2020 17:03:27
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:03:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 4'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '21b24683-0cb6-4780-bb20-35e980b4d394'	System	22 Sep 2020 17:18:40
User entered 'Yes (Y)'	System	22 Sep 2020 17:18:40

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:28', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '21b24683-0cb6-4780-bb20-35e980b4d394'	System	22 Sep 2020 17:18:40
User entered '98.1'	System	22 Sep 2020 17:18:40

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:31', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '21b24683-0cb6-4780-bb20-35e980b4d394'	System	22 Sep 2020 17:18:40
User entered 'No (N)'	System	22 Sep 2020 17:18:40

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:36', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '21b24683-0cb6-4780-bb20-35e980b4d394'	System	22 Sep 2020 17:18:40
User entered '22 Sep 2020 12:18'	System	22 Sep 2020 17:18:40

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 5'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'db68740b-08f1-42f1-b9e5-1b9faa7501d9'	System	23 Sep 2020 17:09:44
User entered 'Yes (Y)'	System	23 Sep 2020 17:09:44

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:32', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'db68740b-08f1-42f1-b9e5-1b9faa7501d9'	System	23 Sep 2020 17:09:44
User entered '98.2'	System	23 Sep 2020 17:09:44

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:35', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'db68740b-08f1-42f1-b9e5-1b9faa7501d9'	System	23 Sep 2020 17:09:44
User entered 'No (N)'	System	23 Sep 2020 17:09:44

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:40', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'db68740b-08f1-42f1-b9e5-1b9faa7501d9'	System	23 Sep 2020 17:09:44
User entered '23 Sep 2020 12:06'	System	23 Sep 2020 17:09:44

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 6'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:22:41', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '9fec3643-22b3-46cc-a986-998a78a13ad7'	System	24 Sep 2020 19:22:59
User entered 'Yes (Y)'	System	24 Sep 2020 19:22:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:22:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '9fec3643-22b3-46cc-a986-998a78a13ad7'	System	24 Sep 2020 19:22:59
User entered '98.3'	System	24 Sep 2020 19:22:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:22:50', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '9fec3643-22b3-46cc-a986-998a78a13ad7'	System	24 Sep 2020 19:22:59
User entered 'No (N)'	System	24 Sep 2020 19:22:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:22:54', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '9fec3643-22b3-46cc-a986-998a78a13ad7'	System	24 Sep 2020 19:22:59
User entered '24 Sep 2020 14:22'	System	24 Sep 2020 19:22:59

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 7'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:13', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f455c4d5-4586-445e-a9b8-7f0626f5fdc6'	System	25 Sep 2020 17:02:42
User entered 'Yes (Y)'	System	25 Sep 2020 17:02:42

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:21', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f455c4d5-4586-445e-a9b8-7f0626f5fdc6'	System	25 Sep 2020 17:02:42
User entered '98.0'	System	25 Sep 2020 17:02:42

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:25', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f455c4d5-4586-445e-a9b8-7f0626f5fdc6'	System	25 Sep 2020 17:02:42
User entered 'No (N)'	System	25 Sep 2020 17:02:42

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:27', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f455c4d5-4586-445e-a9b8-7f0626f5fdc6'	System	25 Sep 2020 17:02:42
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:02:42

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:54:55', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '884ca1bc-c744-4120-a764-ed9a6efe6409'	System	19 Sep 2020 15:55:26
User entered 'None (1)'	System	19 Sep 2020 15:55:26

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:10', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '884ca1bc-c744-4120-a764-ed9a6efe6409'	System	19 Sep 2020 15:55:26
User entered 'No (N)'	System	19 Sep 2020 15:55:26

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '884ca1bc-c744-4120-a764-ed9a6efe6409'	System	19 Sep 2020 15:55:26
User entered 'No (N)'	System	19 Sep 2020 15:55:26

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:19', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '884ca1bc-c744-4120-a764-ed9a6efe6409'	System	19 Sep 2020 15:55:26
User entered 'None (1)'	System	19 Sep 2020 15:55:26

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:24', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '884ca1bc-c744-4120-a764-ed9a6efe6409'	System	19 Sep 2020 15:55:26
User entered '19 Sep 2020 10:55'	System	19 Sep 2020 15:55:26

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 10:44'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 13:14'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:15', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a3e7e91f-256d-45f8-ae92-cd4dc7f30b80'	System	20 Sep 2020 14:49:33
User entered 'None (1)'	System	20 Sep 2020 14:49:33

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:18', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a3e7e91f-256d-45f8-ae92-cd4dc7f30b80'	System	20 Sep 2020 14:49:33
User entered 'No (N)'	System	20 Sep 2020 14:49:33

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:21', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a3e7e91f-256d-45f8-ae92-cd4dc7f30b80'	System	20 Sep 2020 14:49:33
User entered 'No (N)'	System	20 Sep 2020 14:49:33

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:25', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a3e7e91f-256d-45f8-ae92-cd4dc7f30b80'	System	20 Sep 2020 14:49:33
User entered 'None (1)'	System	20 Sep 2020 14:49:33

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:28', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a3e7e91f-256d-45f8-ae92-cd4dc7f30b80'	System	20 Sep 2020 14:49:33
User entered '20 Sep 2020 09:49'	System	20 Sep 2020 14:49:33

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 14:09'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 2'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:22', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '75472603-72be-4ca8-9402-14793f69c67a'	System	20 Sep 2020 17:01:58
User entered 'None (1)'	System	20 Sep 2020 17:01:58

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:32', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '75472603-72be-4ca8-9402-14793f69c67a'	System	20 Sep 2020 17:01:58
User entered 'No (N)'	System	20 Sep 2020 17:01:58

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:35', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '75472603-72be-4ca8-9402-14793f69c67a'	System	20 Sep 2020 17:01:58
User entered 'No (N)'	System	20 Sep 2020 17:01:58

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:38', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '75472603-72be-4ca8-9402-14793f69c67a'	System	20 Sep 2020 17:01:58
User entered 'None (1)'	System	20 Sep 2020 17:01:58

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:41', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '75472603-72be-4ca8-9402-14793f69c67a'	System	20 Sep 2020 17:01:58
User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:01:58

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 3'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:00:54', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '1b2867d1-f5e0-49fc-9bba-5f67a860ce38'	System	21 Sep 2020 17:04:09
User entered 'None (1)'	System	21 Sep 2020 17:04:09

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:00:57', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '1b2867d1-f5e0-49fc-9bba-5f67a860ce38'	System	21 Sep 2020 17:04:09
User entered 'No (N)'	System	21 Sep 2020 17:04:09

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '1b2867d1-f5e0-49fc-9bba-5f67a860ce38'	System	21 Sep 2020 17:04:09
User entered 'No (N)'	System	21 Sep 2020 17:04:09

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:03', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '1b2867d1-f5e0-49fc-9bba-5f67a860ce38'	System	21 Sep 2020 17:04:09
User entered 'None (1)'	System	21 Sep 2020 17:04:09

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:07', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '1b2867d1-f5e0-49fc-9bba-5f67a860ce38'	System	21 Sep 2020 17:04:09
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:09

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 4'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:43', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd4fbb157-3e94-4b41-ac4f-a06d2721df47'	System	22 Sep 2020 17:19:01
User entered 'None (1)'	System	22 Sep 2020 17:19:01

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:46', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd4fbb157-3e94-4b41-ac4f-a06d2721df47'	System	22 Sep 2020 17:19:01
User entered 'No (N)'	System	22 Sep 2020 17:19:01

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:48', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd4fbb157-3e94-4b41-ac4f-a06d2721df47'	System	22 Sep 2020 17:19:01
User entered 'No (N)'	System	22 Sep 2020 17:19:01

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:51', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd4fbb157-3e94-4b41-ac4f-a06d2721df47'	System	22 Sep 2020 17:19:01
User entered 'None (1)'	System	22 Sep 2020 17:19:01

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:18:57', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd4fbb157-3e94-4b41-ac4f-a06d2721df47'	System	22 Sep 2020 17:19:01
User entered '22 Sep 2020 12:18'	System	22 Sep 2020 17:19:01

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 5'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:46', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '99c110e0-4b17-47d1-bd7e-8f02fcc69455'	System	23 Sep 2020 17:09:54
User entered 'None (1)'	System	23 Sep 2020 17:09:54

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:49', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '99c110e0-4b17-47d1-bd7e-8f02fcc69455'	System	23 Sep 2020 17:09:54
User entered 'No (N)'	System	23 Sep 2020 17:09:54

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:51', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '99c110e0-4b17-47d1-bd7e-8f02fcc69455'	System	23 Sep 2020 17:09:54
User entered 'No (N)'	System	23 Sep 2020 17:09:54

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:54', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '99c110e0-4b17-47d1-bd7e-8f02fcc69455'	System	23 Sep 2020 17:09:54
User entered 'None (1)'	System	23 Sep 2020 17:09:54

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:06:57', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '99c110e0-4b17-47d1-bd7e-8f02fcc69455'	System	23 Sep 2020 17:09:54
User entered '23 Sep 2020 12:06'	System	23 Sep 2020 17:09:54

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 6'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:02', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'c06d34c0-da08-478d-9477-6838c1075506'	System	24 Sep 2020 19:23:24
User entered 'None (1)'	System	24 Sep 2020 19:23:24

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:09', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'c06d34c0-da08-478d-9477-6838c1075506'	System	24 Sep 2020 19:23:24
User entered 'No (N)'	System	24 Sep 2020 19:23:24

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'c06d34c0-da08-478d-9477-6838c1075506'	System	24 Sep 2020 19:23:24
User entered 'No (N)'	System	24 Sep 2020 19:23:24

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:16', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'c06d34c0-da08-478d-9477-6838c1075506'	System	24 Sep 2020 19:23:24
User entered 'None (1)'	System	24 Sep 2020 19:23:24

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:22', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'c06d34c0-da08-478d-9477-6838c1075506'	System	24 Sep 2020 19:23:24
User entered '24 Sep 2020 14:23'	System	24 Sep 2020 19:23:24

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 7'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:34', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fe7f045b-fed1-4d9f-b644-d22e787b734b'	System	25 Sep 2020 17:03:11
User entered 'None (1)'	System	25 Sep 2020 17:03:11

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:43', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fe7f045b-fed1-4d9f-b644-d22e787b734b'	System	25 Sep 2020 17:03:11
User entered 'No (N)'	System	25 Sep 2020 17:03:11

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:45', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fe7f045b-fed1-4d9f-b644-d22e787b734b'	System	25 Sep 2020 17:03:11
User entered 'No (N)'	System	25 Sep 2020 17:03:11

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fe7f045b-fed1-4d9f-b644-d22e787b734b'	System	25 Sep 2020 17:03:11
User entered 'None (1)'	System	25 Sep 2020 17:03:11

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:50', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fe7f045b-fed1-4d9f-b644-d22e787b734b'	System	25 Sep 2020 17:03:11
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:03:11

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:30', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '5f2dfac0-7079-4583-843f-d914128a3db7'	System	19 Sep 2020 15:55:53
User entered 'None (0)'	System	19 Sep 2020 15:55:53

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:33', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '5f2dfac0-7079-4583-843f-d914128a3db7'	System	19 Sep 2020 15:55:53
User entered 'None (0)'	System	19 Sep 2020 15:55:53

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:35', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '5f2dfac0-7079-4583-843f-d914128a3db7'	System	19 Sep 2020 15:55:53
User entered 'None (0)'	System	19 Sep 2020 15:55:53

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:38', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '5f2dfac0-7079-4583-843f-d914128a3db7'	System	19 Sep 2020 15:55:53
User entered 'None (0)'	System	19 Sep 2020 15:55:53

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:40', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '5f2dfac0-7079-4583-843f-d914128a3db7'	System	19 Sep 2020 15:55:53
User entered 'None (0)'	System	19 Sep 2020 15:55:53

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:43', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '5f2dfac0-7079-4583-843f-d914128a3db7'	System	19 Sep 2020 15:55:53
User entered 'None (0)'	System	19 Sep 2020 15:55:53

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '5f2dfac0-7079-4583-843f-d914128a3db7'	System	19 Sep 2020 15:55:53
User entered 'No (N)'	System	19 Sep 2020 15:55:53

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-19T10:55:50', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '5f2dfac0-7079-4583-843f-d914128a3db7'	System	19 Sep 2020 15:55:53
User entered '19 Sep 2020 10:55'	System	19 Sep 2020 15:55:53

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 10:44'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 13:14'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:42', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'cabd156d-39e6-4b4f-bc65-325de64a9425'	System	20 Sep 2020 14:50:10
User entered 'No interference with activity (1)'	System	20 Sep 2020 14:50:10

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:45', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'cabd156d-39e6-4b4f-bc65-325de64a9425'	System	20 Sep 2020 14:50:10
User entered 'None (0)'	System	20 Sep 2020 14:50:10

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'cabd156d-39e6-4b4f-bc65-325de64a9425'	System	20 Sep 2020 14:50:10
User entered 'None (0)'	System	20 Sep 2020 14:50:10

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:51', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'cabd156d-39e6-4b4f-bc65-325de64a9425'	System	20 Sep 2020 14:50:10
User entered 'None (0)'	System	20 Sep 2020 14:50:10

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:54', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'cabd156d-39e6-4b4f-bc65-325de64a9425'	System	20 Sep 2020 14:50:10
User entered 'None (0)'	System	20 Sep 2020 14:50:10

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:49:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'cabd156d-39e6-4b4f-bc65-325de64a9425'	System	20 Sep 2020 14:50:10
User entered 'None (0)'	System	20 Sep 2020 14:50:10

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:50:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'cabd156d-39e6-4b4f-bc65-325de64a9425'	System	20 Sep 2020 14:50:10
User entered 'No (N)'	System	20 Sep 2020 14:50:10

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T09:50:03', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'cabd156d-39e6-4b4f-bc65-325de64a9425'	System	20 Sep 2020 14:50:10
User entered '20 Sep 2020 09:50'	System	20 Sep 2020 14:50:10

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Sep 2020 14:09'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 2'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6de9fd09-98a7-4900-9524-f3a10ebea145'	System	20 Sep 2020 17:02:23
User entered 'No interference with activity (1)'	System	20 Sep 2020 17:02:23

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:49', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6de9fd09-98a7-4900-9524-f3a10ebea145'	System	20 Sep 2020 17:02:23
User entered 'None (0)'	System	20 Sep 2020 17:02:23

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:51', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6de9fd09-98a7-4900-9524-f3a10ebea145'	System	20 Sep 2020 17:02:23
User entered 'None (0)'	System	20 Sep 2020 17:02:23

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:53', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6de9fd09-98a7-4900-9524-f3a10ebea145'	System	20 Sep 2020 17:02:23
User entered 'None (0)'	System	20 Sep 2020 17:02:23

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6de9fd09-98a7-4900-9524-f3a10ebea145'	System	20 Sep 2020 17:02:23
User entered 'None (0)'	System	20 Sep 2020 17:02:23

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:01:58', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6de9fd09-98a7-4900-9524-f3a10ebea145'	System	20 Sep 2020 17:02:23
User entered 'None (0)'	System	20 Sep 2020 17:02:23

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:02:01', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6de9fd09-98a7-4900-9524-f3a10ebea145'	System	20 Sep 2020 17:02:23
User entered 'No (N)'	System	20 Sep 2020 17:02:23

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-20T12:02:04', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6de9fd09-98a7-4900-9524-f3a10ebea145'	System	20 Sep 2020 17:02:23
User entered '20 Sep 2020 12:02'	System	20 Sep 2020 17:02:23

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 3'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'bbf2c59c-f076-4a87-96d1-cbaa493dcb28'	System	21 Sep 2020 17:04:45
User entered 'None (0)'	System	21 Sep 2020 17:04:45

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:14', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'bbf2c59c-f076-4a87-96d1-cbaa493dcb28'	System	21 Sep 2020 17:04:45
User entered 'None (0)'	System	21 Sep 2020 17:04:45

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:16', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'bbf2c59c-f076-4a87-96d1-cbaa493dcb28'	System	21 Sep 2020 17:04:45
User entered 'None (0)'	System	21 Sep 2020 17:04:45

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:18', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'bbf2c59c-f076-4a87-96d1-cbaa493dcb28'	System	21 Sep 2020 17:04:45
User entered 'None (0)'	System	21 Sep 2020 17:04:45

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:20', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'bbf2c59c-f076-4a87-96d1-cbaa493dcb28'	System	21 Sep 2020 17:04:45
User entered 'None (0)'	System	21 Sep 2020 17:04:45

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:23', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'bbf2c59c-f076-4a87-96d1-cbaa493dcb28'	System	21 Sep 2020 17:04:45
User entered 'None (0)'	System	21 Sep 2020 17:04:45

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:26', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'bbf2c59c-f076-4a87-96d1-cbaa493dcb28'	System	21 Sep 2020 17:04:45
User entered 'No (N)'	System	21 Sep 2020 17:04:45

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-21T12:01:32', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'bbf2c59c-f076-4a87-96d1-cbaa493dcb28'	System	21 Sep 2020 17:04:45
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:45

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 4'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:19:04', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'feed2776-abf5-4443-bcb6-835e46c54dd2'	System	22 Sep 2020 17:19:25
User entered 'None (0)'	System	22 Sep 2020 17:19:25

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:19:06', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'feed2776-abf5-4443-bcb6-835e46c54dd2'	System	22 Sep 2020 17:19:25
User entered 'None (0)'	System	22 Sep 2020 17:19:25

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:19:08', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'feed2776-abf5-4443-bcb6-835e46c54dd2'	System	22 Sep 2020 17:19:25
User entered 'None (0)'	System	22 Sep 2020 17:19:25

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:19:10', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'feed2776-abf5-4443-bcb6-835e46c54dd2'	System	22 Sep 2020 17:19:25
User entered 'None (0)'	System	22 Sep 2020 17:19:25

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:19:13', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'feed2776-abf5-4443-bcb6-835e46c54dd2'	System	22 Sep 2020 17:19:25
User entered 'None (0)'	System	22 Sep 2020 17:19:25

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:19:15', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'feed2776-abf5-4443-bcb6-835e46c54dd2'	System	22 Sep 2020 17:19:25
User entered 'None (0)'	System	22 Sep 2020 17:19:25

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:19:18', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'feed2776-abf5-4443-bcb6-835e46c54dd2'	System	22 Sep 2020 17:19:25
User entered 'No (N)'	System	22 Sep 2020 17:19:25

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-22T12:19:21', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'feed2776-abf5-4443-bcb6-835e46c54dd2'	System	22 Sep 2020 17:19:25
User entered '22 Sep 2020 12:19'	System	22 Sep 2020 17:19:25

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 5'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:07:05', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '241f277d-8aed-4200-9dd5-12ae4d23af1b'	System	23 Sep 2020 17:10:19
User entered 'None (0)'	System	23 Sep 2020 17:10:19

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:07:07', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '241f277d-8aed-4200-9dd5-12ae4d23af1b'	System	23 Sep 2020 17:10:19
User entered 'None (0)'	System	23 Sep 2020 17:10:19

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:07:09', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '241f277d-8aed-4200-9dd5-12ae4d23af1b'	System	23 Sep 2020 17:10:19
User entered 'None (0)'	System	23 Sep 2020 17:10:19

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:07:11', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '241f277d-8aed-4200-9dd5-12ae4d23af1b'	System	23 Sep 2020 17:10:19
User entered 'None (0)'	System	23 Sep 2020 17:10:19

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:07:13', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '241f277d-8aed-4200-9dd5-12ae4d23af1b'	System	23 Sep 2020 17:10:19
User entered 'None (0)'	System	23 Sep 2020 17:10:19

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:07:15', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '241f277d-8aed-4200-9dd5-12ae4d23af1b'	System	23 Sep 2020 17:10:19
User entered 'None (0)'	System	23 Sep 2020 17:10:19

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:07:18', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '241f277d-8aed-4200-9dd5-12ae4d23af1b'	System	23 Sep 2020 17:10:19
User entered 'No (N)'	System	23 Sep 2020 17:10:19

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-23T12:07:21', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '241f277d-8aed-4200-9dd5-12ae4d23af1b'	System	23 Sep 2020 17:10:19
User entered '23 Sep 2020 12:07'	System	23 Sep 2020 17:10:19

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 6'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:28', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4326cabf-8ea4-4cbb-917e-548006c7343c'	System	24 Sep 2020 19:23:56
User entered 'None (0)'	System	24 Sep 2020 19:23:56

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:30', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4326cabf-8ea4-4cbb-917e-548006c7343c'	System	24 Sep 2020 19:23:56
User entered 'None (0)'	System	24 Sep 2020 19:23:56

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:33', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4326cabf-8ea4-4cbb-917e-548006c7343c'	System	24 Sep 2020 19:23:56
User entered 'None (0)'	System	24 Sep 2020 19:23:56

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:36', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4326cabf-8ea4-4cbb-917e-548006c7343c'	System	24 Sep 2020 19:23:56
User entered 'None (0)'	System	24 Sep 2020 19:23:56

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:38', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4326cabf-8ea4-4cbb-917e-548006c7343c'	System	24 Sep 2020 19:23:56
User entered 'None (0)'	System	24 Sep 2020 19:23:56

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:40', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4326cabf-8ea4-4cbb-917e-548006c7343c'	System	24 Sep 2020 19:23:56
User entered 'None (0)'	System	24 Sep 2020 19:23:56

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:45', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4326cabf-8ea4-4cbb-917e-548006c7343c'	System	24 Sep 2020 19:23:56
User entered 'No (N)'	System	24 Sep 2020 19:23:56

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-24T14:23:54', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4326cabf-8ea4-4cbb-917e-548006c7343c'	System	24 Sep 2020 19:23:56
User entered '24 Sep 2020 14:23'	System	24 Sep 2020 19:23:56

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 7'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:01:57', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4699e4b1-4313-43ff-a8f4-b8aceb8fb35e'	System	25 Sep 2020 17:03:21
User entered 'None (0)'	System	25 Sep 2020 17:03:21

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:02:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4699e4b1-4313-43ff-a8f4-b8aeeb8fb35e'	System	25 Sep 2020 17:03:21
User entered 'None (0)'	System	25 Sep 2020 17:03:21

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:02:02', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4699e4b1-4313-43ff-a8f4-b8aeeb8fb35e'	System	25 Sep 2020 17:03:21
User entered 'None (0)'	System	25 Sep 2020 17:03:21

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:02:04', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4699e4b1-4313-43ff-a8f4-b8aeeb8fb35e'	System	25 Sep 2020 17:03:21
User entered 'None (0)'	System	25 Sep 2020 17:03:21

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:02:06', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4699e4b1-4313-43ff-a8f4-b8aceb8fb35e'	System	25 Sep 2020 17:03:21
User entered 'None (0)'	System	25 Sep 2020 17:03:21

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:02:07', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4699e4b1-4313-43ff-a8f4-b8aeeb8fb35e'	System	25 Sep 2020 17:03:21
User entered 'None (0)'	System	25 Sep 2020 17:03:21

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:02:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4699e4b1-4313-43ff-a8f4-b8aceb8fb35e'	System	25 Sep 2020 17:03:21
User entered 'No (N)'	System	25 Sep 2020 17:03:21

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-09-25T12:02:14', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4699e4b1-4313-43ff-a8f4-b8aeeb8fb35e'	System	25 Sep 2020 17:03:21
User entered '25 Sep 2020 12:02'	System	25 Sep 2020 17:03:21

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 15:26:27

US3552473

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	26 Sep 2020 19:08:47

US3552473

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '26 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	26 Sep 2020 19:08:47

US3552473

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	26 Sep 2020 19:08:47

US3552473

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	26 Sep 2020 19:08:47

US3552473

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Oct 2020 16:10:51

US3552473

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'l'	System	03 Oct 2020 16:10:51

US3552473

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Oct 2020 16:10:58

US3552473

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	09 Nov 2020 19:27:18
User entered '3 Oct 2020'	(b) (4)	
	Mikayla Frye (b) (4)	03 Oct 2020 16:10:58
	(b) (4)	

US3552473

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Oct 2020 16:10:58

US3552473

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Oct 2020 16:10:58

US3552473

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:00:42

US3552473

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'l'	System	12 Oct 2020 17:00:42

US3552473

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:00:52

US3552473

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '12 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:00:52

US3552473

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:00:52

US3552473

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:00:52

US3552473

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Janice Tennant (b) (4)	14 Oct 2020 15:05:48

US3552473

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'I'	System	14 Oct 2020 15:05:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:21:55

US3552473

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:21:55

US3552473

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:21:55

US3552473

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'VISIT2'	System	14 Oct 2020 16:21:55

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09:25'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered '14 Oct 2020 09:25'	System	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '97.7' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '89'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'bpm'	System	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'breaths/min'	System	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '130'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'mmHg'	System	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '88'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'mmHg'	System	14 Oct 2020 16:22:18

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '11:00'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered '14 Oct 2020 11:00'	System	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '98.1' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '89'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'bpm'	System	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'breaths/min'	System	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '131'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'mmHg'	System	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '83'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'mmHg'	System	14 Oct 2020 16:22:48

US3552473

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:57

US3552473

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:22:57

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Janice Tennant (b) (4)	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Janice Tennant (b) (4)	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Janice Tennant (b) (4)	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14 Oct 2020'	(b) (4) Janice Tennant (b) (4)	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '10:26'	(b) (4) Janice Tennant (b) (4)	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered '14 Oct 2020 10:26'	System	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) Janice Tennant (b) (4)	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'ONCE'	System	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 15:30:04

US3552473

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:23:09

US3552473

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:23:09

US3552473

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '10:00'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:23:09

US3552473

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered '14 Oct 2020 10:00'	System	14 Oct 2020 16:23:09

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '10:01'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered '14 Oct 2020 10:01'	System	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered empty.	System	14 Oct 2020 16:23:22

US3552473

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Oct 2020 15:11:11

US3552473

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'I'	System	21 Oct 2020 15:11:11

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:50:22', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0c74e67c-fcc4-46a0-b279-8dce80873efb'	System	14 Oct 2020 15:50:41
User entered 'Yes (Y)'	System	14 Oct 2020 15:50:41

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:50:28', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0c74e67c-fcc4-46a0-b279-8dce80873efb'	System	14 Oct 2020 15:50:41
User entered '98.1'	System	14 Oct 2020 15:50:41

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:50:33', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0c74e67c-fcc4-46a0-b279-8dce80873efb'	System	14 Oct 2020 15:50:41
User entered 'No (N)'	System	14 Oct 2020 15:50:41

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:50:37', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0c74e67c-fcc4-46a0-b279-8dce80873efb'	System	14 Oct 2020 15:50:41
User entered '14 Oct 2020 10:50'	System	14 Oct 2020 15:50:41

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 10:46'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 13:16'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:36:27', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689230ec-0fd2-413f-b871-2fcf3f765a36'	System	14 Oct 2020 20:36:51
User entered 'Yes (Y)'	System	14 Oct 2020 20:36:51

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:36:35', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689230ec-0fd2-413f-b871-2fcf3f765a36'	System	14 Oct 2020 20:36:51
User entered '98.1'	System	14 Oct 2020 20:36:51

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:36:43', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689230ec-0fd2-413f-b871-2fcf3f765a36'	System	14 Oct 2020 20:36:51
User entered 'No (N)'	System	14 Oct 2020 20:36:51

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:36:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689230ec-0fd2-413f-b871-2fcf3f765a36'	System	14 Oct 2020 20:36:51
User entered '14 Oct 2020 15:36'	System	14 Oct 2020 20:36:51

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 14:11'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 2'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:06:43', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7f30d2cb-8a44-41d0-8bf3-81da6cd5469f'	System	15 Oct 2020 17:07:11
User entered 'Yes (Y)'	System	15 Oct 2020 17:07:11

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:06:54', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7f30d2cb-8a44-41d0-8bf3-81da6cd5469f'	System	15 Oct 2020 17:07:11
User entered '97.9'	System	15 Oct 2020 17:07:11

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:06:59', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7f30d2cb-8a44-41d0-8bf3-81da6cd5469f'	System	15 Oct 2020 17:07:11
User entered 'No (N)'	System	15 Oct 2020 17:07:11

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:04', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7f30d2cb-8a44-41d0-8bf3-81da6cd5469f'	System	15 Oct 2020 17:07:11
User entered '15 Oct 2020 12:07'	System	15 Oct 2020 17:07:11

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 3'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:11:30', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b354b8e4-de3a-4c05-aff4-84f93565e240'	System	16 Oct 2020 18:11:53
User entered 'Yes (Y)'	System	16 Oct 2020 18:11:53

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:11:42', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b354b8e4-de3a-4c05-aff4-84f93565e240'	System	16 Oct 2020 18:11:53
User entered '99.3'	System	16 Oct 2020 18:11:53

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:11:46', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b354b8e4-de3a-4c05-aff4-84f93565e240'	System	16 Oct 2020 18:11:53
User entered 'No (N)'	System	16 Oct 2020 18:11:53

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:11:49', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b354b8e4-de3a-4c05-aff4-84f93565e240'	System	16 Oct 2020 18:11:53
User entered '16 Oct 2020 13:11'	System	16 Oct 2020 18:11:53

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 4'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:05:50', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a55cfd8b-ba32-4465-9711-034e1b3d073c'	System	17 Oct 2020 20:06:07
User entered 'Yes (Y)'	System	17 Oct 2020 20:06:07

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:05:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a55cfd8b-ba32-4465-9711-034e1b3d073c'	System	17 Oct 2020 20:06:07
User entered '96.4'	System	17 Oct 2020 20:06:07

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:05:59', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a55cfd8b-ba32-4465-9711-034e1b3d073c'	System	17 Oct 2020 20:06:07
User entered 'No (N)'	System	17 Oct 2020 20:06:07

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:06:02', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a55cfd8b-ba32-4465-9711-034e1b3d073c'	System	17 Oct 2020 20:06:07
User entered '17 Oct 2020 15:06'	System	17 Oct 2020 20:06:07

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 5'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:01:59', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fa81c139-8b5e-44f9-9af4-4615567852e3'	System	18 Oct 2020 17:02:27
User entered 'Yes (Y)'	System	18 Oct 2020 17:02:27

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:02:17', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fa81c139-8b5e-44f9-9af4-4615567852e3' User entered '97.7'	System	18 Oct 2020 17:02:27
	System	18 Oct 2020 17:02:27

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:02:20', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fa81c139-8b5e-44f9-9af4-4615567852e3'	System	18 Oct 2020 17:02:27
User entered 'No (N)'	System	18 Oct 2020 17:02:27

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:02:23', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'fa81c139-8b5e-44f9-9af4-4615567852e3'	System	18 Oct 2020 17:02:27
User entered '18 Oct 2020 12:02'	System	18 Oct 2020 17:02:27

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 6'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:16', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '79efbc68-2e46-4a18-bcbc-fde21bc48ccd'	System	19 Oct 2020 17:33:13
User entered 'Yes (Y)'	System	19 Oct 2020 17:33:13

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:24', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '79efbc68-2e46-4a18-bcbc-fde21bc48ccd'	System	19 Oct 2020 17:33:13
User entered '98.4'	System	19 Oct 2020 17:33:13

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:27', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '79efbc68-2e46-4a18-bcbc-fde21bc48ccd'	System	19 Oct 2020 17:33:13
User entered 'No (N)'	System	19 Oct 2020 17:33:13

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:31', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '79efbc68-2e46-4a18-bcbc-fde21bc48ccd'	System	19 Oct 2020 17:33:13
User entered '19 Oct 2020 12:31'	System	19 Oct 2020 17:33:13

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 7'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:10:35', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f8eda2c7-0df8-4ec2-a65b-363c0f0e9985'	System	20 Oct 2020 20:10:51
User entered 'Yes (Y)'	System	20 Oct 2020 20:10:51

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:10:41', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f8eda2c7-0df8-4ec2-a65b-363c0f0e9985'	System	20 Oct 2020 20:10:51
User entered '97.9'	System	20 Oct 2020 20:10:51

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:10:44', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f8eda2c7-0df8-4ec2-a65b-363c0f0e9985'	System	20 Oct 2020 20:10:51
User entered 'No (N)'	System	20 Oct 2020 20:10:51

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:10:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f8eda2c7-0df8-4ec2-a65b-363c0f0e9985'	System	20 Oct 2020 20:10:51
User entered '20 Oct 2020 15:10'	System	20 Oct 2020 20:10:51

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:50:48', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '07660e33-a3cc-4bbc-a80c-c1eda59c0d0b'	System	14 Oct 2020 15:51:10
User entered 'None (1)'	System	14 Oct 2020 15:51:10

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:50:52', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '07660e33-a3cc-4bbc-a80c-c1eda59c0d0b'	System	14 Oct 2020 15:51:10
User entered 'No (N)'	System	14 Oct 2020 15:51:10

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:50:55', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '07660e33-a3cc-4bbc-a80c-c1eda59c0d0b'	System	14 Oct 2020 15:51:10
User entered 'No (N)'	System	14 Oct 2020 15:51:10

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:50:59', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '07660e33-a3cc-4bbc-a80c-c1eda59c0d0b'	System	14 Oct 2020 15:51:10
User entered 'None (1)'	System	14 Oct 2020 15:51:10

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:02', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '07660e33-a3cc-4bbc-a80c-c1eda59c0d0b'	System	14 Oct 2020 15:51:10
User entered '14 Oct 2020 10:51'	System	14 Oct 2020 15:51:10

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 10:46'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 13:16'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:58', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a36a5f9b-f671-4011-9bea-ed50188759d1'	System	14 Oct 2020 20:36:12
User entered 'None (1)'	System	14 Oct 2020 20:36:12

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a36a5f9b-f671-4011-9bea-ed50188759d1'	System	14 Oct 2020 20:36:12
User entered 'No (N)'	System	14 Oct 2020 20:36:12

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:36:01', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a36a5f9b-f671-4011-9bea-ed50188759d1'	System	14 Oct 2020 20:36:12
User entered 'No (N)'	System	14 Oct 2020 20:36:12

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:36:05', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a36a5f9b-f671-4011-9bea-ed50188759d1'	System	14 Oct 2020 20:36:12
User entered 'None (1)'	System	14 Oct 2020 20:36:12

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:36:08', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a36a5f9b-f671-4011-9bea-ed50188759d1'	System	14 Oct 2020 20:36:12
User entered '14 Oct 2020 15:36'	System	14 Oct 2020 20:36:12

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 14:11'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 2'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:09', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '509a412e-4a82-42c9-bf88-e2df41e3a086'	System	15 Oct 2020 17:07:37
User entered 'None (1)'	System	15 Oct 2020 17:07:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:13', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '509a412e-4a82-42c9-bf88-e2df41e3a086'	System	15 Oct 2020 17:07:37
User entered 'No (N)'	System	15 Oct 2020 17:07:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:20', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '509a412e-4a82-42c9-bf88-e2df41e3a086'	System	15 Oct 2020 17:07:37
User entered 'No (N)'	System	15 Oct 2020 17:07:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:29', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '509a412e-4a82-42c9-bf88-e2df41e3a086'	System	15 Oct 2020 17:07:37
User entered 'None (1)'	System	15 Oct 2020 17:07:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:31', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '509a412e-4a82-42c9-bf88-e2df41e3a086'	System	15 Oct 2020 17:07:37
User entered '15 Oct 2020 12:07'	System	15 Oct 2020 17:07:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 3'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:22', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7362c861-466f-4c7e-ad5b-c8ffc0d4d73b'	System	16 Oct 2020 18:12:37
User entered 'None (1)'	System	16 Oct 2020 18:12:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:25', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7362c861-466f-4c7e-ad5b-c8ffc0d4d73b'	System	16 Oct 2020 18:12:37
User entered 'No (N)'	System	16 Oct 2020 18:12:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:28', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7362c861-466f-4c7e-ad5b-c8ffc0d4d73b'	System	16 Oct 2020 18:12:37
User entered 'No (N)'	System	16 Oct 2020 18:12:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:30', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7362c861-466f-4c7e-ad5b-c8ffc0d4d73b'	System	16 Oct 2020 18:12:37
User entered 'None (1)'	System	16 Oct 2020 18:12:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:33', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '7362c861-466f-4c7e-ad5b-c8ffc0d4d73b'	System	16 Oct 2020 18:12:37
User entered '16 Oct 2020 13:12'	System	16 Oct 2020 18:12:37

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 4'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:06:08', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b7db3568-3e46-445b-9472-6cc649fe7123'	System	17 Oct 2020 20:06:28
User entered 'None (1)'	System	17 Oct 2020 20:06:28

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:06:11', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b7db3568-3e46-445b-9472-6cc649fe7123'	System	17 Oct 2020 20:06:28
User entered 'No (N)'	System	17 Oct 2020 20:06:28

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:06:18', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b7db3568-3e46-445b-9472-6cc649fe7123'	System	17 Oct 2020 20:06:28
User entered 'No (N)'	System	17 Oct 2020 20:06:28

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:06:22', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b7db3568-3e46-445b-9472-6cc649fe7123'	System	17 Oct 2020 20:06:28
User entered 'None (1)'	System	17 Oct 2020 20:06:28

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:06:24', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b7db3568-3e46-445b-9472-6cc649fe7123'	System	17 Oct 2020 20:06:28
User entered '17 Oct 2020 15:06'	System	17 Oct 2020 20:06:28

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 5'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:02:36', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '650e6091-115f-42f2-809f-ab48c3730c78'	System	18 Oct 2020 17:03:11
User entered 'None (1)'	System	18 Oct 2020 17:03:11

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:02:46', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '650e6091-115f-42f2-809f-ab48c3730c78'	System	18 Oct 2020 17:03:11
User entered 'No (N)'	System	18 Oct 2020 17:03:11

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:02:52', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '650e6091-115f-42f2-809f-ab48c3730c78'	System	18 Oct 2020 17:03:11
User entered 'No (N)'	System	18 Oct 2020 17:03:11

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:03', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '650e6091-115f-42f2-809f-ab48c3730c78'	System	18 Oct 2020 17:03:11
User entered 'None (1)'	System	18 Oct 2020 17:03:11

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:06', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '650e6091-115f-42f2-809f-ab48c3730c78'	System	18 Oct 2020 17:03:11
User entered '18 Oct 2020 12:03'	System	18 Oct 2020 17:03:11

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 6'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:45', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '27bab321-6838-42fd-95d9-5b7fa72c48f6'	System	19 Oct 2020 17:33:24
User entered 'None (1)'	System	19 Oct 2020 17:33:24

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:43', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '27bab321-6838-42fd-95d9-5b7fa72c48f6'	System	19 Oct 2020 17:33:24
User entered 'No (N)'	System	19 Oct 2020 17:33:24

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:49', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '27bab321-6838-42fd-95d9-5b7fa72c48f6'	System	19 Oct 2020 17:33:24
User entered 'No (N)'	System	19 Oct 2020 17:33:24

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:52', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '27bab321-6838-42fd-95d9-5b7fa72c48f6'	System	19 Oct 2020 17:33:24
User entered 'None (1)'	System	19 Oct 2020 17:33:24

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:31:57', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '27bab321-6838-42fd-95d9-5b7fa72c48f6'	System	19 Oct 2020 17:33:24
User entered '19 Oct 2020 12:31'	System	19 Oct 2020 17:33:24

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 7'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:10:54', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689e8df2-56e6-4902-af0d-11ee63550231'	System	20 Oct 2020 20:11:13
User entered 'None (1)'	System	20 Oct 2020 20:11:13

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:10:59', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689e8df2-56e6-4902-af0d-11ee63550231'	System	20 Oct 2020 20:11:13
User entered 'No (N)'	System	20 Oct 2020 20:11:13

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:03', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689e8df2-56e6-4902-af0d-11ee63550231'	System	20 Oct 2020 20:11:13
User entered 'No (N)'	System	20 Oct 2020 20:11:13

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:06', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689e8df2-56e6-4902-af0d-11ee63550231'	System	20 Oct 2020 20:11:13
User entered 'None (1)'	System	20 Oct 2020 20:11:13

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:09', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '689e8df2-56e6-4902-af0d-11ee63550231'	System	20 Oct 2020 20:11:13
User entered '20 Oct 2020 15:11'	System	20 Oct 2020 20:11:13

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e79e0537-b05a-4fd3-96ca-962396380e0e'	System	14 Oct 2020 15:51:41
User entered 'No interference with activity (1)'	System	14 Oct 2020 15:51:41

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:18', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e79e0537-b05a-4fd3-96ca-962396380e0e'	System	14 Oct 2020 15:51:41
User entered 'None (0)'	System	14 Oct 2020 15:51:41

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:21', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e79e0537-b05a-4fd3-96ca-962396380e0e'	System	14 Oct 2020 15:51:41
User entered 'None (0)'	System	14 Oct 2020 15:51:41

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:23', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e79e0537-b05a-4fd3-96ca-962396380e0e'	System	14 Oct 2020 15:51:41
User entered 'None (0)'	System	14 Oct 2020 15:51:41

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:26', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e79e0537-b05a-4fd3-96ca-962396380e0e'	System	14 Oct 2020 15:51:41
User entered 'None (0)'	System	14 Oct 2020 15:51:41

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:28', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e79e0537-b05a-4fd3-96ca-962396380e0e'	System	14 Oct 2020 15:51:41
User entered 'None (0)'	System	14 Oct 2020 15:51:41

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:32', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e79e0537-b05a-4fd3-96ca-962396380e0e'	System	14 Oct 2020 15:51:41
User entered 'No (N)'	System	14 Oct 2020 15:51:41

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T10:51:34', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e79e0537-b05a-4fd3-96ca-962396380e0e'	System	14 Oct 2020 15:51:41
User entered '14 Oct 2020 10:51'	System	14 Oct 2020 15:51:41

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 10:46'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 13:16'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:34:59', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '227739dc-93e3-40bb-b619-c8e77fd4edcb'	System	14 Oct 2020 20:35:50
User entered 'No interference with activity (1)'	System	14 Oct 2020 20:35:50

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:10', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '227739dc-93e3-40bb-b619-c8e77fd4edcb'	System	14 Oct 2020 20:35:50
User entered 'None (0)'	System	14 Oct 2020 20:35:50

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:16', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '227739dc-93e3-40bb-b619-c8e77fd4edcb' User entered 'None (0)'	System	14 Oct 2020 20:35:50
	System	14 Oct 2020 20:35:50

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:23', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '227739dc-93e3-40bb-b619-c8e77fd4edcb' User entered 'None (0)'	System	14 Oct 2020 20:35:50
	System	14 Oct 2020 20:35:50

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:35', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '227739dc-93e3-40bb-b619-c8e77fd4edcb'	System	14 Oct 2020 20:35:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	14 Oct 2020 20:35:50

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:38', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '227739dc-93e3-40bb-b619-c8e77fd4edcb'	System	14 Oct 2020 20:35:50
User entered 'None (0)'	System	14 Oct 2020 20:35:50

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:42', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '227739dc-93e3-40bb-b619-c8e77fd4edcb'	System	14 Oct 2020 20:35:50
User entered 'No (N)'	System	14 Oct 2020 20:35:50

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-14T15:35:46', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '227739dc-93e3-40bb-b619-c8e77fd4edcb'	System	14 Oct 2020 20:35:50
User entered '14 Oct 2020 15:35'	System	14 Oct 2020 20:35:50

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '14 Oct 2020 14:11'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 2'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:38', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '120e61b3-2bc2-4257-b4b5-34cd9aadf656'	System	15 Oct 2020 17:08:29
User entered 'None (0)'	System	15 Oct 2020 17:08:29

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:51', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '120e61b3-2bc2-4257-b4b5-34cd9aadf656'	System	15 Oct 2020 17:08:29
User entered 'No interference with activity (1)'	System	15 Oct 2020 17:08:29

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:07:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '120e61b3-2bc2-4257-b4b5-34cd9aadf656'	System	15 Oct 2020 17:08:29
User entered 'None (0)'	System	15 Oct 2020 17:08:29

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:08:15', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '120e61b3-2bc2-4257-b4b5-34cd9aadf656'	System	15 Oct 2020 17:08:29
User entered 'No interference with activity (1)'	System	15 Oct 2020 17:08:29

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:08:18', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '120e61b3-2bc2-4257-b4b5-34cd9aadf656'	System	15 Oct 2020 17:08:29
User entered 'None (0)'	System	15 Oct 2020 17:08:29

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:08:21', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '120e61b3-2bc2-4257-b4b5-34cd9aadf656'	System	15 Oct 2020 17:08:29
User entered 'None (0)'	System	15 Oct 2020 17:08:29

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:08:24', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '120e61b3-2bc2-4257-b4b5-34cd9aadf656'	System	15 Oct 2020 17:08:29
User entered 'No (N)'	System	15 Oct 2020 17:08:29

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-15T12:08:27', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '120e61b3-2bc2-4257-b4b5-34cd9aadf656'	System	15 Oct 2020 17:08:29
User entered '15 Oct 2020 12:08'	System	15 Oct 2020 17:08:29

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 3'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:11:55', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '81b10706-a6d0-40e0-b232-0451091ed1de' User entered 'None (0)'	System	16 Oct 2020 18:12:20
	System	16 Oct 2020 18:12:20

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:11:58', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '81b10706-a6d0-40e0-b232-0451091ed1de'	System	16 Oct 2020 18:12:20
User entered 'No interference with activity (1)'	System	16 Oct 2020 18:12:20

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:01', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '81b10706-a6d0-40e0-b232-0451091ed1de'	System	16 Oct 2020 18:12:20
User entered 'No interference with activity (1)'	System	16 Oct 2020 18:12:20

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:04', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '81b10706-a6d0-40e0-b232-0451091ed1de' User entered 'None (0)'	System	16 Oct 2020 18:12:20
	System	16 Oct 2020 18:12:20

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:08', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '81b10706-a6d0-40e0-b232-0451091ed1de' User entered 'None (0)'	System	16 Oct 2020 18:12:20
	System	16 Oct 2020 18:12:20

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:11', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '81b10706-a6d0-40e0-b232-0451091ed1de'	System	16 Oct 2020 18:12:20
User entered 'None (0)'	System	16 Oct 2020 18:12:20

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:14', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '81b10706-a6d0-40e0-b232-0451091ed1de'	System	16 Oct 2020 18:12:20
User entered 'No (N)'	System	16 Oct 2020 18:12:20

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-16T13:12:17', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '81b10706-a6d0-40e0-b232-0451091ed1de' User entered '16 Oct 2020 13:12'	System	16 Oct 2020 18:12:20
	System	16 Oct 2020 18:12:20

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 4'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:06:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8de8d033-c02a-44c7-a174-2e9e2e440b7b'	System	17 Oct 2020 20:08:22
User entered 'No interference with activity (1)'	System	17 Oct 2020 20:08:22

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:07:21', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8de8d033-c02a-44c7-a174-2e9e2e440b7b'	System	17 Oct 2020 20:08:22
User entered 'No interference with activity (1)'	System	17 Oct 2020 20:08:22

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:08:02', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8de8d033-c02a-44c7-a174-2e9e2e440b7b'	System	17 Oct 2020 20:08:22
User entered 'No interference with activity (1)'	System	17 Oct 2020 20:08:22

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:08:06', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8de8d033-c02a-44c7-a174-2e9e2e440b7b'	System	17 Oct 2020 20:08:22
User entered 'None (0)'	System	17 Oct 2020 20:08:22

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:08:09', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8de8d033-c02a-44c7-a174-2e9e2e440b7b'	System	17 Oct 2020 20:08:22
User entered 'None (0)'	System	17 Oct 2020 20:08:22

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:08:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8de8d033-c02a-44c7-a174-2e9e2e440b7b'	System	17 Oct 2020 20:08:22
User entered 'None (0)'	System	17 Oct 2020 20:08:22

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:08:17', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8de8d033-c02a-44c7-a174-2e9e2e440b7b'	System	17 Oct 2020 20:08:22
User entered 'No (N)'	System	17 Oct 2020 20:08:22

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-17T15:08:19', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8de8d033-c02a-44c7-a174-2e9e2e440b7b'	System	17 Oct 2020 20:08:22
User entered '17 Oct 2020 15:08'	System	17 Oct 2020 20:08:22

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 5'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:17', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8efcda52-ad67-4665-9798-78ff136b6668'	System	18 Oct 2020 17:03:40
User entered 'None (0)'	System	18 Oct 2020 17:03:40

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:20', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8efcda52-ad67-4665-9798-78ff136b6668'	System	18 Oct 2020 17:03:40
User entered 'None (0)'	System	18 Oct 2020 17:03:40

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:22', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8efcda52-ad67-4665-9798-78ff136b6668'	System	18 Oct 2020 17:03:40
User entered 'None (0)'	System	18 Oct 2020 17:03:40

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:24', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8efcda52-ad67-4665-9798-78ff136b6668'	System	18 Oct 2020 17:03:40
User entered 'None (0)'	System	18 Oct 2020 17:03:40

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:25', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8efcda52-ad67-4665-9798-78ff136b6668'	System	18 Oct 2020 17:03:40
User entered 'None (0)'	System	18 Oct 2020 17:03:40

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:27', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8efcda52-ad67-4665-9798-78ff136b6668'	System	18 Oct 2020 17:03:40
User entered 'None (0)'	System	18 Oct 2020 17:03:40

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:32', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8efcda52-ad67-4665-9798-78ff136b6668'	System	18 Oct 2020 17:03:40
User entered 'No (N)'	System	18 Oct 2020 17:03:40

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-18T12:03:35', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '8efcda52-ad67-4665-9798-78ff136b6668'	System	18 Oct 2020 17:03:40
User entered '18 Oct 2020 12:03'	System	18 Oct 2020 17:03:40

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 6'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:32:03', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '289630d2-0f19-4071-91b6-21d1f6fee246'	System	19 Oct 2020 17:33:30
User entered 'None (0)'	System	19 Oct 2020 17:33:30

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:32:05', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '289630d2-0f19-4071-91b6-21d1f6fee246'	System	19 Oct 2020 17:33:30
User entered 'None (0)'	System	19 Oct 2020 17:33:30

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:32:07', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '289630d2-0f19-4071-91b6-21d1f6fee246'	System	19 Oct 2020 17:33:30
User entered 'None (0)'	System	19 Oct 2020 17:33:30

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:32:09', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '289630d2-0f19-4071-91b6-21d1f6fee246'	System	19 Oct 2020 17:33:30
User entered 'None (0)'	System	19 Oct 2020 17:33:30

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:32:11', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '289630d2-0f19-4071-91b6-21d1f6fee246'	System	19 Oct 2020 17:33:30
User entered 'None (0)'	System	19 Oct 2020 17:33:30

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:32:14', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '289630d2-0f19-4071-91b6-21d1f6fee246'	System	19 Oct 2020 17:33:30
User entered 'None (0)'	System	19 Oct 2020 17:33:30

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:32:17', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '289630d2-0f19-4071-91b6-21d1f6fee246'	System	19 Oct 2020 17:33:30
User entered 'No (N)'	System	19 Oct 2020 17:33:30

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-19T12:32:20', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '289630d2-0f19-4071-91b6-21d1f6fee246'	System	19 Oct 2020 17:33:30
User entered '19 Oct 2020 12:32'	System	19 Oct 2020 17:33:30

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
Data entry locked.	System	14 Oct 2020 15:30:04
User entered 'Day 7'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:16', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53d1a74e-421b-43cf-b1c0-994f0b7aef2f'	System	20 Oct 2020 20:11:36
User entered 'None (0)'	System	20 Oct 2020 20:11:36

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:19', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53d1a74e-421b-43cf-b1c0-994f0b7aef2f'	System	20 Oct 2020 20:11:36
User entered 'None (0)'	System	20 Oct 2020 20:11:36

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:21', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53d1a74e-421b-43cf-b1c0-994f0b7aef2f' User entered 'None (0)'	System	20 Oct 2020 20:11:36
	System	20 Oct 2020 20:11:36

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:22', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53d1a74e-421b-43cf-b1c0-994f0b7aef2f' User entered 'None (0)'	System	20 Oct 2020 20:11:36
	System	20 Oct 2020 20:11:36

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:24', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53d1a74e-421b-43cf-b1c0-994f0b7aef2f' User entered 'None (0)'	System	20 Oct 2020 20:11:36
	System	20 Oct 2020 20:11:36

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:27', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53d1a74e-421b-43cf-b1c0-994f0b7aef2f'	System	20 Oct 2020 20:11:36
User entered 'None (0)'	System	20 Oct 2020 20:11:36

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

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 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:30', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53d1a74e-421b-43cf-b1c0-994f0b7aef2f'	System	20 Oct 2020 20:11:36
User entered 'No (N)'	System	20 Oct 2020 20:11:36

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-10-20T15:11:33', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53d1a74e-421b-43cf-b1c0-994f0b7aef2f'	System	20 Oct 2020 20:11:36
User entered '20 Oct 2020 15:11'	System	20 Oct 2020 20:11:36

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:30:04

US3552473

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:28:57
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:30:04

US3552473

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Oct 2020 15:11:20

US3552473

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Oct 2020 15:11:20

US3552473

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Oct 2020 15:11:20

US3552473

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Oct 2020 15:11:20

US3552473

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 14:55:17

US3552473

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'l'	System	28 Oct 2020 14:55:17

US3552473

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 14:55:25

US3552473

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '28 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 14:55:25

US3552473

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 14:55:25

US3552473

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Oct 2020 14:55:25

US3552473

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 17:37:28

US3552473

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'l'	System	04 Nov 2020 17:37:28

US3552473

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 17:37:39

US3552473

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	09 Nov 2020 19:27:29
User entered '4 Nov 2020'	(b) (4)	
	Mikayla Frye (b) (4)	04 Nov 2020 17:37:39
	(b) (4)	

US3552473

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 17:37:39

US3552473

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 17:37:39

US3552473

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:34

US3552473

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'l'	System	09 Nov 2020 16:08:34

US3552473

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:45

US3552473

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:45

US3552473

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:45

US3552473

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'VISIT3'	System	09 Nov 2020 16:08:45

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered empty.	System	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered empty.	System	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered empty.	System	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered empty.	System	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered empty.	System	09 Nov 2020 16:08:52

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34

US3552473

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34

US3552473

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:57

US3552473

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:08:57

US3552473

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:09:12

US3552473

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:09:12

US3552473

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09:14'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 16:09:12

US3552473

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered '09 Nov 2020 09:14'	System	09 Nov 2020 16:09:12

US3552473

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Dec 2020 15:54:48

US3552473

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:34
User entered 'I'	System	09 Dec 2020 15:54:48

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05
Data entry locked.	System	19 Sep 2020 15:26:27
User entered 'Day 64'	System	19 Sep 2020 15:26:27

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Have you been exposed to someone with 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)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Have you experienced any new COVID-19 disease symptoms 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)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Have you had to contact a healthcare provider 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)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05
Data entry locked.	System	19 Sep 2020 15:26:27
User entered '19 Nov 2020 00:01'	System	19 Sep 2020 15:26:27

US3552473

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:47:05
Data entry locked.	System	19 Sep 2020 15:26:27
User entered '23 Nov 2020 23:59'	System	19 Sep 2020 15:26:27

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (2dae65d4609b7901)', Time: '2020-11-26T10:50:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd3ad5f83-8d14-4562-9709-42b558960562'	System	26 Nov 2020 16:52:11
User entered 'Yes (Y)'	System	26 Nov 2020 16:52:11

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (2dae65d4609b7901)', Time: '2020-11-26T10:51:02', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd3ad5f83-8d14-4562-9709-42b558960562'	System	26 Nov 2020 16:52:11
User entered 'No (N)'	System	26 Nov 2020 16:52:11

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Have you experienced any new COVID-19 disease symptoms 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 (2dae65d4609b7901)', Time: '2020-11-26T10:51:40', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd3ad5f83-8d14-4562-9709-42b558960562'	System	26 Nov 2020 16:52:11
User entered 'No (N)'	System	26 Nov 2020 16:52:11

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Have you had to contact a healthcare provider 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 (2dae65d4609b7901)', Time: '2020-11-26T10:51:46', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd3ad5f83-8d14-4562-9709-42b558960562'	System	26 Nov 2020 16:52:11
User entered 'No (N)'	System	26 Nov 2020 16:52:11

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2dae65d4609b7901)', Time: '2020-11-26T10:52:06', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd3ad5f83-8d14-4562-9709-42b558960562'	System	26 Nov 2020 16:52:11
User entered '26 Nov 2020 10:52:06'	System	26 Nov 2020 16:52:11

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:02:21
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'AE #1' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 22:42:58
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2020-12-04T13:23:01', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f7bde394-fca7-4fce-a698-28814abda451'	System	04 Dec 2020 19:23:44
User entered 'Yes (Y)'	System	04 Dec 2020 19:23:44

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (d22933deae7b78e1)', Time: '2020-12-04T13:23:05', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f7bde394-fca7-4fce-a698-28814abda451'	System	04 Dec 2020 19:23:44
User entered 'No (N)'	System	04 Dec 2020 19:23:44

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Have you experienced any new COVID-19 disease symptoms 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 (d22933deae7b78e1)', Time: '2020-12-04T13:23:11', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f7bde394-fca7-4fce-a698-28814abda451'	System	04 Dec 2020 19:23:44
User entered 'No (N)'	System	04 Dec 2020 19:23:44

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Have you had to contact a healthcare provider 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 (d22933deae7b78e1)', Time: '2020-12-04T13:23:19', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f7bde394-fca7-4fce-a698-28814abda451'	System	04 Dec 2020 19:23:44
User entered 'Yes (Y)'	System	04 Dec 2020 19:23:44

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2020-12-04T13:23:27', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f7bde394-fca7-4fce-a698-28814abda451'	System	04 Dec 2020 19:23:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 19:23:44

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2020-12-04T13:23:31', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'f7bde394-fca7-4fce-a698-28814abda451'	System	04 Dec 2020 19:23:44
User entered '04 Dec 2020 13:23:31'	System	04 Dec 2020 19:23:44

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (d22933deae7b78e1)', Time: '2020-12-07T05:14:10', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a7faa82f-8869-466e-b37d-fef39a9b1610'	System	07 Dec 2020 11:14:35
User entered 'No (N)'	System	07 Dec 2020 11:14:35

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (d22933deae7b78e1)', Time: '2020-12-07T05:14:24', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a7faa82f-8869-466e-b37d-fef39a9b1610'	System	07 Dec 2020 11:14:35
User entered 'No (N)'	System	07 Dec 2020 11:14:35

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2020-12-07T05:14:31', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a7faa82f-8869-466e-b37d-fef39a9b1610'	System	07 Dec 2020 11:14:35
User entered '07 Dec 2020 05:14:31'	System	07 Dec 2020 11:14:35

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (d22933deae7b78e1)', Time: '2020-12-14T07:59:19', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd43d3ddf-ee03-41f4-b167-712ca747a030'	System	14 Dec 2020 13:59:35
User entered 'No (N)'	System	14 Dec 2020 13:59:35

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (d22933deae7b78e1)', Time: '2020-12-14T07:59:28', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd43d3ddf-ee03-41f4-b167-712ca747a030'	System	14 Dec 2020 13:59:35
User entered 'No (N)'	System	14 Dec 2020 13:59:35

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2020-12-14T07:59:32', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd43d3ddf-ee03-41f4-b167-712ca747a030'	System	14 Dec 2020 13:59:35
User entered '14 Dec 2020 07:59:32'	System	14 Dec 2020 13:59:35

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (d22933deae7b78e1)', Time: '2020-12-21T08:14:38', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd8da990e-af3f-49d1-955f-31a6e53f9f9d'	System	21 Dec 2020 14:15:06
User entered 'No (N)'	System	21 Dec 2020 14:15:06

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (d22933deae7b78e1)', Time: '2020-12-21T08:14:56', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd8da990e-af3f-49d1-955f-31a6e53f9f9d'	System	21 Dec 2020 14:15:06
User entered 'No (N)'	System	21 Dec 2020 14:15:06

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2020-12-21T08:15:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd8da990e-af3f-49d1-955f-31a6e53f9f9d'	System	21 Dec 2020 14:15:06
User entered '21 Dec 2020 08:15:00'	System	21 Dec 2020 14:15:06

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (d22933deae7b78e1)', Time: '2021-01-04T08:31:17', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '1d04687a-946f-472e-977f-43a86b61a75f'	System	04 Jan 2021 14:31:40
User entered 'No (N)'	System	04 Jan 2021 14:31:40

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (d22933deae7b78e1)', Time: '2021-01-04T08:31:30', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '1d04687a-946f-472e-977f-43a86b61a75f'	System	04 Jan 2021 14:31:40
User entered 'No (N)'	System	04 Jan 2021 14:31:40

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2021-01-04T08:31:35', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '1d04687a-946f-472e-977f-43a86b61a75f' User entered '04 Jan 2021 08:31:35'	System	04 Jan 2021 14:31:40

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (d22933deae7b78e1)', Time: '2021-01-11T18:04:51', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0cb39f05-7e82-47b7-ad58-57b830467eac'	System	12 Jan 2021 00:05:24
User entered 'No (N)'	System	12 Jan 2021 00:05:24

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (d22933deae7b78e1)', Time: '2021-01-11T18:04:57', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0cb39f05-7e82-47b7-ad58-57b830467eac'	System	12 Jan 2021 00:05:24
User entered 'No (N)'	System	12 Jan 2021 00:05:24

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2021-01-11T18:05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0cb39f05-7e82-47b7-ad58-57b830467eac'	System	12 Jan 2021 00:05:24
User entered '11 Jan 2021 18:05:00'	System	12 Jan 2021 00:05:24

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (d22933deae7b78e1)', Time: '2021-01-21T18:37:25', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '716c039b-e886-4a19-8c6c-cda9ed6f7434'	System	22 Jan 2021 00:38:00
User entered 'No (N)'	System	22 Jan 2021 00:38:00

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (d22933deae7b78e1)', Time: '2021-01-21T18:37:39', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '716c039b-e886-4a19-8c6c-cda9ed6f7434'	System	22 Jan 2021 00:38:00
User entered 'Yes (Y)'	System	22 Jan 2021 00:38:00

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2021-01-21T18:37:47', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '716c039b-e886-4a19-8c6c-cda9ed6f7434'	System	22 Jan 2021 00:38:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 00:38:00

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2021-01-21T18:37:50', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '716c039b-e886-4a19-8c6c-cda9ed6f7434'	System	22 Jan 2021 00:38:00
User entered '21 Jan 2021 18:37:50'	System	22 Jan 2021 00:38:00

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (d22933deae7b78e1)', Time: '2021-01-25T18:44:48', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a1000148-8892-41ff-9c6b-15927103e37b'	System	26 Jan 2021 00:45:16
User entered 'No (N)'	System	26 Jan 2021 00:45:16

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (d22933deae7b78e1)', Time: '2021-01-25T18:45:07', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a1000148-8892-41ff-9c6b-15927103e37b'	System	26 Jan 2021 00:45:16
User entered 'No (N)'	System	26 Jan 2021 00:45:16

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d22933deae7b78e1)', Time: '2021-01-25T18:45:12', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'a1000148-8892-41ff-9c6b-15927103e37b'	System	26 Jan 2021 00:45:16
User entered '25 Jan 2021 18:45:12'	System	26 Jan 2021 00:45:16

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-02-01T15:37:29', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4586c584-048b-40d3-ab7a-3d22a54d0170'	System	01 Feb 2021 21:37:41
User entered 'No (N)'	System	01 Feb 2021 21:37:41

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-02-01T15:37:34', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4586c584-048b-40d3-ab7a-3d22a54d0170'	System	01 Feb 2021 21:37:41
User entered 'No (N)'	System	01 Feb 2021 21:37:41

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-02-01T15:37:37', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '4586c584-048b-40d3-ab7a-3d22a54d0170'	System	01 Feb 2021 21:37:41
User entered '01 Feb 2021 15:37:37'	System	01 Feb 2021 21:37:41

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-02-08T05:32:07', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '350550c5-056a-4154-bc80-4f01817d24a4'	System	08 Feb 2021 11:32:58
User entered 'No (N)'	System	08 Feb 2021 11:32:58

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-02-08T05:32:41', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '350550c5-056a-4154-bc80-4f01817d24a4'	System	08 Feb 2021 11:32:58
User entered 'No (N)'	System	08 Feb 2021 11:32:58

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-02-08T05:32:53', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '350550c5-056a-4154-bc80-4f01817d24a4'	System	08 Feb 2021 11:32:58
User entered '08 Feb 2021 05:32:53'	System	08 Feb 2021 11:32:58

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-02-15T05:23:13', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b4280c7b-b617-4271-a62a-ed12e16d7797'	System	15 Feb 2021 11:23:34
User entered 'No (N)'	System	15 Feb 2021 11:23:34

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-02-15T05:23:19', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b4280c7b-b617-4271-a62a-ed12e16d7797'	System	15 Feb 2021 11:23:34
User entered 'No (N)'	System	15 Feb 2021 11:23:34

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-02-15T05:23:31', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'b4280c7b-b617-4271-a62a-ed12e16d7797'	System	15 Feb 2021 11:23:34
User entered '15 Feb 2021 05:23:31'	System	15 Feb 2021 11:23:34

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-02-22T07:15:58', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e329aeb7-db50-49e7-bc11-feddf0b112ba' User entered 'No (N)'	System	22 Feb 2021 13:16:10

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-02-22T07:16:04', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e329aeb7-db50-49e7-bc11-feddf0b112ba'	System	22 Feb 2021 13:16:10
User entered 'No (N)'	System	22 Feb 2021 13:16:10

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-02-22T07:16:07', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'e329aeb7-db50-49e7-bc11-feddf0b112ba' User entered '22 Feb 2021 07:16:07'	System	22 Feb 2021 13:16:10
	System	22 Feb 2021 13:16:10

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-03-01T02:06:37', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0c65bd4f-da3b-4147-8c32-ab06ffa60193'	System	01 Mar 2021 08:06:49
User entered 'No (N)'	System	01 Mar 2021 08:06:49

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-03-01T02:06:44', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0c65bd4f-da3b-4147-8c32-ab06ffa60193'	System	01 Mar 2021 08:06:49
User entered 'No (N)'	System	01 Mar 2021 08:06:49

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-03-01T02:06:46', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0c65bd4f-da3b-4147-8c32-ab06ffa60193'	System	01 Mar 2021 08:06:49
User entered '01 Mar 2021 02:06:46'	System	01 Mar 2021 08:06:49

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-03-08T03:29:40-06:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53032572-79ee-4f59-bfc5-0c7d15af0078'	System	08 Mar 2021 09:29:59
User entered 'No (N)'	System	08 Mar 2021 09:29:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-03-08T03:29:47-06:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53032572-79ee-4f59-bfc5-0c7d15af0078'	System	08 Mar 2021 09:29:59
User entered 'No (N)'	System	08 Mar 2021 09:29:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-03-08T03:29:52-06:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '53032572-79ee-4f59-bfc5-0c7d15af0078' User entered '08 Mar 2021 03:29:52'	System	08 Mar 2021 09:29:59
	System	08 Mar 2021 09:29:59

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-03-15T07:00:47-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '39993bfe-69ac-43f1-b7e2-457a2551561d' User entered 'No (N)'	System	15 Mar 2021 12:01:07

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-03-15T07:00:56-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '39993bfe-69ac-43f1-b7e2-457a2551561d'	System	15 Mar 2021 12:01:07
User entered 'No (N)'	System	15 Mar 2021 12:01:07

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-03-15T07:00:59-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '39993bfe-69ac-43f1-b7e2-457a2551561d' User entered '15 Mar 2021 07:00:59'	System	15 Mar 2021 12:01:07
	System	15 Mar 2021 12:01:07

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-03-22T08:48:12-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0f47e994-530f-4936-aeae-b12f390cac8c'	System	22 Mar 2021 13:48:23
User entered 'No (N)'	System	22 Mar 2021 13:48:23

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-03-22T08:48:15-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0f47e994-530f-4936-aeae-b12f390cac8c'	System	22 Mar 2021 13:48:23
User entered 'No (N)'	System	22 Mar 2021 13:48:23

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-03-22T08:48:18-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '0f47e994-530f-4936-aeae-b12f390cac8c'	System	22 Mar 2021 13:48:23
User entered '22 Mar 2021 08:48:18'	System	22 Mar 2021 13:48:23

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-03-29T00:50:42-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '089081af-c741-400c-b705-30d7d7e86710'	System	29 Mar 2021 05:51:07
User entered 'No (N)'	System	29 Mar 2021 05:51:07

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-03-29T00:50:56-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '089081af-c741-400c-b705-30d7d7e86710'	System	29 Mar 2021 05:51:07
User entered 'No (N)'	System	29 Mar 2021 05:51:07

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-03-29T00:51:01-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '089081af-c741-400c-b705-30d7d7e86710'	System	29 Mar 2021 05:51:07
User entered '29 Mar 2021 00:51:01'	System	29 Mar 2021 05:51:07

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-04-06T07:46:30-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd21b9d20-c2b0-4ffe-ac91-24b755dd905d' User entered 'No (N)'	System	06 Apr 2021 12:46:40
	System	06 Apr 2021 12:46:40

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-04-06T07:46:33-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd21b9d20-c2b0-4ffe-ac91-24b755dd905d' User entered 'No (N)'	System	06 Apr 2021 12:46:40

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-04-06T07:46:36-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'd21b9d20-c2b0-4ffe-ac91-24b755dd905d' User entered '06 Apr 2021 07:46:36'	System	06 Apr 2021 12:46:40
	System	06 Apr 2021 12:46:40

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-04-12T18:57:51-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'dde86b8c-58de-4188-8826-acc81c5cd9cc' User entered 'No (N)'	System	12 Apr 2021 23:58:02
	System	12 Apr 2021 23:58:02

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-04-12T18:57:55-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'dde86b8c-58de-4188-8826-acc81c5cd9cc'	System	12 Apr 2021 23:58:02
User entered 'No (N)'	System	12 Apr 2021 23:58:02

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-04-12T18:57:58-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'dde86b8c-58de-4188-8826-acc81c5cd9cc'	System	12 Apr 2021 23:58:02
User entered '12 Apr 2021 18:57:58'	System	12 Apr 2021 23:58:02

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-04-19T07:08:19-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6dbce405-c5c1-4132-9c53-d458010cc76c' User entered 'No (N)'	System	19 Apr 2021 12:08:30
	System	19 Apr 2021 12:08:30

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-04-19T07:08:23-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6dbce405-c5c1-4132-9c53-d458010cc76c'	System	19 Apr 2021 12:08:30
User entered 'No (N)'	System	19 Apr 2021 12:08:30

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-04-19T07:08:26-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '6dbce405-c5c1-4132-9c53-d458010cc76c' User entered '19 Apr 2021 07:08:26'	System	19 Apr 2021 12:08:30
	System	19 Apr 2021 12:08:30

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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 (0abb14f6433bc20a)', Time: '2021-04-28T08:36:45-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'df15dc4a-6706-4eab-bd6d-da3ba2de5cfa' User entered 'No (N)'	System	29 Apr 2021 00:50:27

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Have you been exposed to someone with 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 (0abb14f6433bc20a)', Time: '2021-04-28T08:36:48-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'df15dc4a-6706-4eab-bd6d-da3ba2de5cfa' User entered 'No (N)'	System	29 Apr 2021 00:50:27

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-04-28T08:36:50-05:00', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: 'df15dc4a-6706-4eab-bd6d-da3ba2de5cfa' User entered '28 Apr 2021 08:36:50'	System	29 Apr 2021 00:50:27
	System	29 Apr 2021 00:50:27

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '21 Nov 2022 00:01'	System	20 Nov 2020 09:47:05

US3552473

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:47:05
Amendment Manager: User entered '25 Nov 2022 23:59'	System	20 Nov 2020 09:47:05

US3552473

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:17:31

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 16:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-02-28T13:12:58', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '64e11048-b93e-4503-871b-069e07f9b811'	System	28 Feb 2021 19:13:04
User entered 'No (N)'	System	28 Feb 2021 19:13:04

US3552473

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:17:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0abb14f6433bc20a)', Time: '2021-02-28T13:13:01', User OID: 'PatientReportedOutcome (US3552473)', ODM File OID: '64e11048-b93e-4503-871b-069e07f9b811'	System	28 Feb 2021 19:13:04
User entered '28 Feb 2021 13:13:01'	System	28 Feb 2021 19:13:04

US3552473

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Dec 2020 15:54:59

US3552473

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '09 Dec 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Dec 2020 15:54:59

US3552473

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Dec 2020 15:54:59

US3552473

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Dec 2020 15:54:59

US3552473

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 17:46:57

US3552473

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:02
User entered 'l'	System	12 Jan 2021 17:46:57

US3552473

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 17:47:05

US3552473

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 17:47:05

US3552473

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 17:47:05

US3552473

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 17:47:05

US3552473

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 17:31:06

US3552473

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered 'l'	System	11 Feb 2021 17:31:06

US3552473

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 17:32:32

US3552473

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '11 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 17:32:32

US3552473

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 17:32:32

US3552473

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 17:32:32

US3552473

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 21:28:17

US3552473

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered 'l'	System	11 Feb 2021 21:28:17

US3552473

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:43:28
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:58:18

US3552473

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:43:28
User entered '12 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:58:18

US3552473

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:43:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:58:18

US3552473

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:43:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:58:18

US3552473

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:43:28
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:58:21

US3552473

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered 'l'	System	15 Mar 2021 12:58:21

US3552473

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:00

US3552473

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered '29 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:00

US3552473

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[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 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:00

US3552473

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered 'VISIT4'	System	29 Mar 2021 19:05:00

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered empty.	System	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered empty.	System	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered empty.	System	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered empty.	System	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered empty.	System	29 Mar 2021 19:05:03

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39

US3552473

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39

US3552473

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:06

US3552473

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:06

US3552473

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:13

US3552473

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered '29 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:13

US3552473

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered '13:08'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:13

US3552473

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered '29 Mar 2021 13:08'	System	29 Mar 2021 19:05:13

US3552473

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:05:16

US3552473

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:07:39
User entered 'I'	System	29 Mar 2021 19:05:16

US3552473

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:41:55

US3552473

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:41:55

US3552473

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[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 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:41:55

US3552473

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 17:41:55

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:10

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

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 18:05:27
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:43:28
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:44:51

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:10

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:43:28
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 19:44:51

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:10

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:42:10

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:42:10

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:42:10

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:10

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'I'	System	21 Jan 2021 17:42:10

US3552473

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'I'	System	21 Jan 2021 17:42:10

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered empty.	System	21 Jan 2021 17:42:48
DataPoint set to visible.	System	21 Jan 2021 17:42:10

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered empty.	System	21 Jan 2021 17:42:48
DataPoint set to visible.	System	21 Jan 2021 17:42:10

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '08:33'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered '21 Jan 2021 08:33'	System	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '99.2' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '100'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'bpm'	System	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'breaths/min'	System	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '112'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mmHg'	System	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '74'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mmHg'	System	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:42:48

US3552473

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered empty.	System	21 Jan 2021 17:42:48
DataPoint set to visible.	System	21 Jan 2021 17:42:10

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '11:10'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered '21 Jan 2021 11:10'	System	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '98.7' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '100'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'bpm'	System	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'breaths/min'	System	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '137'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mmHg'	System	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '79'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:43:17

US3552473

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mmHg'	System	21 Jan 2021 17:43:17

US3552473

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:25

US3552473

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:25

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 17:43:39

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:39

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:39

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mRNA-1273'	System	21 Jan 2021 17:43:39
DataPoint set to visible.	System	21 Jan 2021 17:42:10

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:39

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '10:40'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:39

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered '21 Jan 2021 10:40'	System	21 Jan 2021 17:43:39

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:39

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'ONCE'	System	21 Jan 2021 17:43:39

US3552473

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 17:43:39

US3552473

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:51

US3552473

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:51

US3552473

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '08:24'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:43:51

US3552473

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered '21 Jan 2021 08:24'	System	21 Jan 2021 17:43:51

US3552473

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:44:00

US3552473

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:44:00

US3552473

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '08:28'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 17:44:00

US3552473

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered '21 Jan 2021 08:28'	System	21 Jan 2021 17:44:00

US3552473

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

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 14:34:47

US3552473

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

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'I'	System	01 Feb 2021 14:34:47

US3552473

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 14:35:47

US3552473

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '29 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 14:35:47

US3552473

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Contact Not Made (CONTACT NOT MADE)'	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 14:35:47

US3552473

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Never returned any calls/messages we left.'	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 14:35:47

US3552473

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 21:28:25

US3552473

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'l'	System	11 Feb 2021 21:28:25

US3552473

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'I'	System	11 Feb 2021 21:28:25
DataPoint set to visible.	System	11 Feb 2021 21:28:25

US3552473

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:12:56

US3552473

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '18 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:12:56

US3552473

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[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 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:12:56

US3552473

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'OLD29'	System	19 Feb 2021 13:12:56

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '18 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '13:50'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered '18 Feb 2021 13:50'	System	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '97.8' F	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '83'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'bpm'	System	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'breaths/min'	System	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '128'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mmHg'	System	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '92'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mmHg'	System	19 Feb 2021 13:13:17

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '18 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14:28'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered '18 Feb 2021 14:28'	System	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '98.5' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '86'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'bpm'	System	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'breaths/min'	System	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '124'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mmHg'	System	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '88'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mmHg'	System	19 Feb 2021 13:13:38

US3552473

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:45

US3552473

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '18 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:45

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'mRNA-1273'	System	19 Feb 2021 13:13:57
DataPoint set to visible.	System	11 Feb 2021 21:28:25

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '18 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '13:58'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered '18 Feb 2021 13:58'	System	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'ONCE'	System	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 13:13:57

US3552473

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Feb 2021 13:14:02

US3552473

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'l'	System	19 Feb 2021 13:14:02

US3552473

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:31:53
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	25 Feb 2021 21:33:18

US3552473

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:31:53
User entered '25 Feb 2021'	Cassandra Zehenny (b) (4) (b) (4)	25 Feb 2021 21:33:18

US3552473

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:31:53
User entered 'Contact Made (CONTACT MADE)'	Cassandra Zehenny (b) (4) (b) (4)	25 Feb 2021 21:33:18

US3552473

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:31:53
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	25 Feb 2021 21:33:18

US3552473

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:31:53
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	25 Feb 2021 21:33:24

US3552473

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:05:27
User entered 'l'	System	25 Feb 2021 21:33:24

US3552473

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 19:04:34

US3552473

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered '29 Mar 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:34

US3552473

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:34

US3552473

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 19:04:34

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:04:37

US3552473

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:40

US3552473

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:40

US3552473

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:48

US3552473

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered '29 Mar 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:48

US3552473

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered '13:08'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:04:48

US3552473

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:08'	System	29 Mar 2021 19:04:48

US3552473

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:17:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:52:20
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	04 Dec 2020 20:09:36

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 19:56:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:37:47
User entered	System	05 Dec 2020 18:37:39
'USA-US089-2020-mRNA-1273-P301000015'		
User entered 'New'	(b) (4), (b) (6)	05 Dec 2020 18:37:39

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:39
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Perirectal abscess, LLT: Perirectal abscess - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:12:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 18:12:42
Data point term sent to Coder	System	07 Dec 2020 18:03:44
Coding entries removed.	Cassandra Zehenny (b) (4)	07 Dec 2020 18:03:25
	(b) (4)	
User entered 'perirectal abscess' reason for change: New Information	Cassandra Zehenny (b) (4)	07 Dec 2020 18:03:25
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Colonic abscess, LLT: Colonic abscess - version MedDRA\23.0.	Coder Import (b) (4)	04 Dec 2020 20:15:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Dec 2020 20:15:07
	(b) (4)	
Data point term sent to Coder	System	04 Dec 2020 20:14:05
User entered 'Colon abscess'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:42
User entered 'Yes (Y)'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:43
User entered 'No (N)'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:45
User entered 'No (N)'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:16:30
User closed query 'Per source and medical records , subject experienced symptoms starting 22Nov2020. Please reconcile. ' (Site from CRA).		09 Dec 2020 20:16:29
Query 'Per source and medical records , subject experienced symptoms starting 22Nov2020. Please reconcile. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	09 Dec 2020 20:14:53
User entered '22 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	09 Dec 2020 20:13:14
User opened query 'Per source and medical records , subject experienced symptoms starting 22Nov2020. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:52:45
User entered '24 Nov 2020'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:47
User entered empty.	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 20:13:07

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:59:28
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	04 Dec 2020 21:05:41
User entered 'Yes (Y)'	(b) (4)	
	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:59:29
User entered '01 Dec 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	04 Dec 2020 21:05:41
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:59:31
User entered empty.	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 20:13:07

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:59:33
User entered 'Grade 4 (Grade 4)'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:52
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	04 Dec 2020 20:13:54
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	04 Dec 2020 20:13:07
User entered 'Yes (Y)'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:59:47
User entered '0'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:59:48
User entered '0'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:59:50
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		04 Dec 2020 20:13:54
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		04 Dec 2020 20:13:54
User entered '1' reason for change: Data Entry Error Heather Douds	(b) (4)	04 Dec 2020 20:13:54
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	04 Dec 2020 20:13:07
User entered '0'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:53:14
User entered '24 Nov 2020'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:53:16
User entered '25 Nov 2020'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 19:56:16
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	04 Dec 2020 20:13:07

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:18
User entered empty.	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:19
User entered '0'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:21
User entered '0'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:23
User entered '0'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 19:53:20
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:04:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:04:58
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	04 Dec 2020 21:04:58
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 20:13:07
User entered empty.	Heather Douds (b) (4) (b) (4)	04 Dec 2020 20:13:07

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:04:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:04:58
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4)	04 Dec 2020 21:04:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 20:13:07
User entered empty.	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 19:53:23
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Douds (b) (4) (b) (4)	04 Dec 2020 20:13:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:25
User entered '0'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:27
User entered '1' reason for change: New Information	Cassandra Zehenny (b) (4)	04 Dec 2020 21:04:58
User entered '0'	(b) (4)	
	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:28
User entered 'l'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:59:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Cassandra Zehenny (b) (4)	04 Dec 2020 21:05:41
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

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 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:56:30
User entered empty.	Heather Douds (b) (4)	04 Dec 2020 20:13:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, diagnostic is an available option in Con Proc ecrf. Review SAE Narrative= CT Scan and Standard Laboratory Test if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:42:54
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, diagnostic is an available option in Con Proc ecrf. Review SAE Narrative= CT Scan and Standard Laboratory Test if this should be recorded. Else, re-clarify.' answered with 'per PI we are not recording these as Con Procedures. They are listed in the narrative but will not be added to con procedure list. thank you. ' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4) 25 Feb 2021 22:02:45
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, diagnostic is an available option in Con Proc ecrf. Review SAE Narrative= CT Scan and Standard Laboratory Test if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:25:34
User closed query 'Per DM CLR: Narrative indicates that the subject had CT Scan and Standard Laboratory Test. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the correpsnding procedures as appropriate. Otherwise, clarify.' (Site from DM).		24 Feb 2021 07:25:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Query 'Per DM CLR: Narrative indicates that the subject had CT Scan and Standard Laboratory Test. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the correpsnding procedures as appropriate. Otherwise, clarify.' answered with 'These are non-invasive diagnostic tests, not conprocedures. ' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4) 04 Feb 2021 22:38:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject had CT Scan and Standard Laboratory Test. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the correpsnding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:11:17
User closed query 'PV Query: Thank you for confirming that prostatitis was a previous diagnosis; please consider adding to the subject's medical history.' (Site from Safety).		04 Jan 2021 15:20:51
Query 'PV Query: Thank you for confirming that prostatitis was a previous diagnosis; please consider adding to the subject's medical history.' answered with 'not reported by subject, thank you' (Site from Safety).	Cassandra Zehenny (b) (4)	30 Dec 2020 16:40:01
User opened query 'PV Query: Thank you for confirming that prostatitis was a previous diagnosis; please consider adding to the subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 21:55:24
User closed query 'PV Query: Please confirm if prostatitis should be added as an SAE.' (Site from Safety).		22 Dec 2020 16:36:35
User closed query 'PV Query: Please provide information on cultures of the purulent drainage.' (Site from Safety).		22 Dec 2020 16:36:28
User closed query 'PV Query: Please provide if there were any underlying causes of perirectal abscess.' (Site from Safety).		22 Dec 2020 16:36:20
Query 'PV Query: Please confirm if prostatitis should be added as an SAE.' answered with 'prostatitis should not be added as SAE. previous diagnosis, not acute' (Site from Safety).	Cassandra Zehenny (b) (4)	21 Dec 2020 16:50:15
Query 'PV Query: Please provide information on cultures of the purulent drainage.' answered with 'no information on cultures provided in medical records, all information obtained is included' (Site from Safety).	Cassandra Zehenny (b) (4)	21 Dec 2020 16:49:55
Query 'PV Query: Please provide if there were any underlying causes of perirectal abscess.' answered with 'unknown cause' (Site from Safety).	Cassandra Zehenny (b) (4)	21 Dec 2020 16:49:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if prostatitis should be added as an SAE.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 20:55:55
User opened query 'PV Query: Please provide information on cultures of the purulent drainage.' (Site from Safety).		18 Dec 2020 20:55:51
User opened query 'PV Query: Please provide if there were any underlying causes of perirectal abscess.' (Site from Safety).		18 Dec 2020 20:55:46
User closed query 'PV Query: Please confirm if COVID testing, as noted in the history and physical, was completed, along with results.' (Site from Safety).		16 Dec 2020 13:36:47
Query 'PV Query: Please confirm if COVID testing, as noted in the history and physical, was completed, along with results.' answered with 'no COVID results were listed in subject's medical record.' (Site from Safety).	Cassandra Zehenny (b) (4)	15 Dec 2020 16:33:56
User opened query 'PV Query: Please confirm if COVID testing, as noted in the history and physical, was completed, along with results.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 12:02:02
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:16:34
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Dec 2020 20:14:45
User entered 'SUBJECT REPORTED HOSPITALIZATION FOR PERIRECTAL ABSCESS. ADMITTED EVENING OF 24NOV FOR RECTAL DISCOMFORT, CT SCAN of abdomen and pelvis with contrast showing 2.5cm perirectal abscess and standard labs drawn. TAKEN TO OR FOR INCISION AND DRAINAGE OF ABSCESS AND THEN DISCHARGED BEFORE LUNCH ON 25NOV. WHILE IN HOSPITAL, SUBJECT RECEIVED ONE DOSE OF UNKNOWN AMOUNTS OF BOTH ROCEPHIN AND ZOSYN. SENT HOME ON ORAL ANTIBIOTICS WHICH SUBJECT HAS SINCE COMPLETED. SUBJECT IS FULLY RECOVERED.' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Dec 2020 20:14:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:59:55
User entered 'SUBJECT REPORTED hospitalization for perirectal abscess. Admitted evening of 24Nov for rectal discomfort, taken to OR for incision and drainage of abscess that night and then discharged before lunch on 25Nov. While in hospital, subject received one dose of unknown amounts of both Rocephin and Zosyn. Sent home on oral antibiotics which subject has since completed. Subject is fully recovered.' reason for change: New Information	Cassandra Zehenny (b) (4)	07 Dec 2020 18:03:25
User entered 'Subject reported having emergent surgery for colon abscess last week (11/24), was discharged next day. Medical records requested, will update when available.'	Heather Douds (b) (4)	04 Dec 2020 20:13:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	04 Dec 2020 20:13:07

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Dec 2020 20:13:07

US3552473

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 20:13:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:17:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:38:25
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	19 Sep 2020 19:38:33
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). ' (Site from DM). Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). ' answered with 'Antiretroviral, not immunosuppressive' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:24:08
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). ' (Site from DM).	Heather Douds (b) (4)	08 Oct 2020 15:52:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: BIKTARVY - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	08 Oct 2020 05:29:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 19:41:48
Data point term sent to Coder User entered 'biktaryv'	(b) (4)	
	System	19 Sep 2020 19:40:58
	Mikayla Frye (b) (4)	19 Sep 2020 19:40:12
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'human immunodeficiency virus'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '50/200/25'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 2017'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:40:12

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Sep 2020 04:28:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 04:28:39
Data point term sent to Coder	System	19 Sep 2020 19:40:58
User entered 'bupropion'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'major clinical depression'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '450'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 2014'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:40:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Sep 2020 19:42:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 19:42:49
Data point term sent to Coder	System	19 Sep 2020 19:42:01
User entered 'clonazepam'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'anxiety'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0.1'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'three times daily (TID)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 2014'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:41:27

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Sep 2020 19:42:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 19:42:49
Data point term sent to Coder	System	19 Sep 2020 19:42:03
User entered 'busprione'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'anxiety'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '5'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un Feb 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:41:56

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Sep 2020 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 19:43:49
Data point term sent to Coder User entered 'ibuprofen'	System Mikayla Frye (b) (4)	19 Sep 2020 19:43:06 19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'generalized aches'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '400'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'as needed (PRN)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 2015'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 19:42:31

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Sep 2020 19:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 19:44:49
Data point term sent to Coder	System	19 Sep 2020 19:44:07
User entered 'multivitamin'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Mikayla Frye (b) (4)	11 Nov 2020 16:21:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'health promotion'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
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)	06 Nov 2020 02:15:25
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 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 16:12:23
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 10:01:54
User entered 'I'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'tablet (TABLET)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 1995'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:43:19

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 19:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 19:44:49
Data point term sent to Coder	System	19 Sep 2020 19:44:07
User entered 'vitamin c'	Mikayla Frye (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Mikayla Frye (b) (4)	11 Nov 2020 16:21:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'health promotion'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '1000'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'un UNK 1995'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:43:51

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
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)	11 Feb 2021 17:35:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 17:35:57
Data point term sent to Coder	System	11 Feb 2021 17:34:39
Coding entries removed.	Stanley Doublin (b) (4)	11 Feb 2021 17:34:06
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)	04 Nov 2020 17:55:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 17:55:25
Data point term sent to Coder	System	04 Nov 2020 17:39:39
User entered 'influenza vaccine'	Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'influenza PROPHYLACTIC' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	11 Feb 2021 17:34:06
User entered 'prophylactic'	(b) (4)	
	Mikayla Frye (b) (4)	04 Nov 2020 17:38:55
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs.' (Site from DM).	(b) (4)	
Query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs.' answered with 'Instructed to enter as "1 injection" by query on subject US3552404. correct as entered' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 03:34:51
Query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs.' answered with 'Instructed to enter as "1 injection" by query on subject US3552404. correct as entered' (Site from DM).	Cassandra Zehenny (b) (4)	22 Jan 2021 22:45:11
User opened query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:12:32
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.		22 Jan 2021 12:12:32
' (Site from DM).		
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.	Cassandra Zehenny (b) (4)	20 Jan 2021 15:37:36
' answered with 'subject reported data, exact dosage unknown' (Site from DM).	(b) (4)	
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.	(b) (4), (b) (6)	19 Jan 2021 05:04:50
' (Site from DM).		
User entered 'I'	Mikayla Frye (b) (4)	04 Nov 2020 17:38:55
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Other (OTHER)'	Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'injection'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'once (ONCE)'	(b) (4) Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Intramuscular (INTRAMUSCULAR)'	Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '30 Oct 2020'	Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '30 Oct 2020'	Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4)	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User entered empty.	System	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User entered empty.	System	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:06
User entered empty.	System	04 Nov 2020 17:38:55

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:01:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:44
Data point term sent to Coder	System	07 Dec 2020 17:52:35
Data point term sent to Coder	System	04 Dec 2020 20:22:11
User entered 'Ciprofloxacin'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:01:58
User entered 'No (N)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:00
User entered 'perirectal abscess' reason for change:	Cassandra Zehenny (b) (4)	07 Dec 2020 17:51:53
Data Entry Error	(b) (4)	
User entered 'Colon abscess'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:01
User entered '500'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:03
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:04
User entered empty.	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:06
User entered 'twice daily (BID)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:08
User entered empty.	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:09
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:10
User entered empty.	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:12
User entered '25 Nov 2020'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:14
User entered '0'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:15
User entered 'No (N)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:16
User entered '01 Dec 2020'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:18
User entered 'No (N)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User entered '2'	System	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User entered 'I'	System	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:08
User entered '804 (804)'	System	04 Dec 2020 20:21:15

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:44
Data point term sent to Coder	System	07 Dec 2020 17:52:34
Data point term sent to Coder	System	04 Dec 2020 20:22:11
User entered 'Metronidazole'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:30
User entered 'No (N)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:38
User entered 'perirectal abscess' reason for change:	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:04
New Information	(b) (4)	
User entered 'Colon abscess'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:39
User entered '500'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:41
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:02:42
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 20:02:42
	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:44
User entered 'three times daily (TID)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:45
User entered empty.	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:47
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:48
User entered empty.	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:50
User entered '25 Nov 2020'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:51
User entered '0'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:53
User entered 'No (N)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:54
User entered '01 Dec 2020'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:56
User entered 'No (N)'	Cassandra Zehenny (b) (4)	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User entered '3'	System	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User entered '1'	System	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:09
User entered '804 (804)'	System	04 Dec 2020 20:22:06

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Dec 2020 14:20:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:20:48
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:02:59
Data point term sent to Coder	System	07 Dec 2020 17:53:35
User entered 'morphine'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:03:00
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:02
User entered 'perirectal abscess'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:04
User entered '4'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:06
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:07
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:09
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:10
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:12
User entered 'Intravenous (INTRAVENOUS)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:13
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:15
User entered '24 Nov 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:16
User entered '0'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:18
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:19
User entered '25 Nov 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:03:21
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User entered empty.	System	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User entered empty.	System	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:11
User entered empty.	System	07 Dec 2020 17:52:39

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CHRONIC OBSTRUCTIVE PULMONARY DISEASE; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:57:05
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CHRONIC OBSTRUCTIVE PULMONARY DISEASE; update Con Med indication or provide clarification. ' answered with 'not worsening, just change in medications' (Site from DM).	Cassandra Zehenny (b) (4)	28 Jan 2021 20:42:09
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CHRONIC OBSTRUCTIVE PULMONARY DISEASE; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 04:17:37
DataPoint Un-verified.		21 Dec 2020 20:54:49
DataPoint Verified.		21 Dec 2020 20:54:45
DataPoint Un-verified.		09 Dec 2020 20:04:21
DataPoint Verified.		09 Dec 2020 20:03:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:44

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	07 Dec 2020 17:53:37
User entered 'Tiotropium'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:20
DataPoint Verified.		09 Dec 2020 20:03:26
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:18
DataPoint Verified.		09 Dec 2020 20:03:27
User entered 'Chronic obstructive pulmonary disease'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:17
DataPoint Verified.		09 Dec 2020 20:03:52
User entered '5'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:16
DataPoint Verified.		09 Dec 2020 20:03:53
User entered 'ug (ug)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:14
DataPoint Verified.		09 Dec 2020 20:03:55
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:13
DataPoint Verified.		09 Dec 2020 20:03:56
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:12
DataPoint Verified.		09 Dec 2020 20:03:58
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:10
DataPoint Verified.		09 Dec 2020 20:03:59
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:09
DataPoint Verified.		09 Dec 2020 20:04:01
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:08
DataPoint Verified.		09 Dec 2020 20:04:03
User entered '13 Oct 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:04:07
DataPoint Verified.		09 Dec 2020 20:04:04
User entered '0'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:53:32

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 17:53:32

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:53:32

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	07 Dec 2020 17:53:32

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 17:53:32

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Dec 2020 17:53:32

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Dec 2020 18:11:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:46
Data point term sent to Coder	System	07 Dec 2020 17:54:37
User entered 'Varenicline'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	28 Jan 2021 20:42:36
User entered 'No (N)'	(b) (4)	
	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4)	01 Feb 2021 11:15:09
Query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'no AE to associate' (Site from DM).	Cassandra Zehenny (b) (4)	28 Jan 2021 20:42:23
User opened query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 04:18:13
User entered 'Smoking cessation'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'mg (mg)'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'once daily (QD)'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'Oral (ORAL)'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '14 Oct 2020'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '28 Oct 2020'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User entered 'I'	System	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User entered 'I'	System	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:05
User entered '804 (804)'	System	07 Dec 2020 17:54:11

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 13:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 13:06:49
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:30
Data point term sent to Coder	System	07 Dec 2020 17:55:38
User entered 'Rocephin'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:35
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:36
User entered 'perirectal abscess'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:39:03
User closed query 'Per DM CLR: Please provide the actual dose for this medication. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		01 Feb 2021 11:07:34
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	28 Jan 2021 20:43:43
User entered 'UNK' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Jan 2021 20:43:43
Query 'Per DM CLR: Please provide the actual dose for this medication. Update the Dose and Dose Unit fields as appropriate.' answered with 'unknown dosage ' (Site from DM).	Cassandra Zehenny (b) (4)	28 Jan 2021 20:43:09
User opened query 'Per DM CLR: Please provide the actual dose for this medication. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 04:18:41
DataPoint Verified.		09 Dec 2020 20:04:38
User entered 'I'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:40
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:42
User entered 'dose'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:43
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 17:54:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 17:54:52
User entered 'once (ONCE)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 17:54:46
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:45
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:46
User entered 'Intravenous (INTRAVENOUS)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:48
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:49
User entered '24 Nov 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:51
User entered '0'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:52
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 17:54:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 17:54:56
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:56
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 17:54:46
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:54
User entered '24 Nov 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:04:55
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User entered empty.	System	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User entered empty.	System	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:07
User entered empty.	System	07 Dec 2020 17:54:46

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User closed query 'Please consider adding lactated ringers IV administered during the hospital stay 24Nov, 25Nov. ' (Site from CRA).	(b) (4)	
Query 'Please consider adding lactated ringers IV administered during the hospital stay 24Nov, 25Nov. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 20:17:22
User opened query 'Please consider adding lactated ringers IV administered during the hospital stay 24Nov, 25Nov. ' (Site from CRA).	Cassandra Zehenny (b) (4)	09 Dec 2020 20:16:07
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:11:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	09 Dec 2020 20:04:59
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:56
Data point term sent to Coder	Coder Import (b) (4)	07 Dec 2020 18:11:56
User entered 'Zosyn'	System	07 Dec 2020 17:55:38
	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:05:05
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:05:07
User entered 'perirectal abscess'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:39:10
User closed query 'Per DM CLR: Please provide the actual dose for this medication. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:07:40
Query 'Per DM CLR: Please provide the actual dose for this medication. Update the Dose and Dose Unit fields as appropriate.' answered with 'unknown dosage' (Site from DM).	Cassandra Zehenny (b) (4)	28 Jan 2021 20:43:35
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	28 Jan 2021 20:43:25
User entered 'UNK' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Jan 2021 20:43:25
User opened query 'Per DM CLR: Please provide the actual dose for this medication. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 04:19:00
DataPoint Verified.		09 Dec 2020 20:05:09
User entered 'I'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:05:11
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:05:59
User entered 'dose'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:06:01
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:06:03
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:06:04
User entered 'Intravenous (INTRAVENOUS)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:06:06
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:06:07
User entered '24 Nov 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:06:09
User entered '0'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:06:10
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:06:12
User entered '24 Nov 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:06:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User entered empty.	System	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User entered empty.	System	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:09
User entered empty.	System	07 Dec 2020 17:55:24

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	21 Dec 2020 20:55:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:22:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:22:48
Data point term sent to Coder	System	09 Dec 2020 20:18:35
User entered 'Lactated Ringers Intravenous fluid'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:03
User entered 'No (N)'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	21 Dec 2020 20:55:05
User entered 'perirectal abscess'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	21 Dec 2020 20:55:07
User entered '350'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	21 Dec 2020 20:55:08
User entered 'mL (mL)'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	21 Dec 2020 20:55:10
User entered empty.	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	21 Dec 2020 20:55:11
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Dec 2020 20:55:11
	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33
	(b) (4)	

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:13
User entered empty.	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:14
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:16
User entered empty.	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:18
User entered '24 Nov 2020'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:19
User entered '0'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:21
User entered 'No (N)'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:22
User entered '25 Nov 2020'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:55:23
User entered 'No (N)'	Cassandra Zehenny (b) (4)	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User entered empty.	System	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User entered empty.	System	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:38:11
User entered empty.	System	09 Dec 2020 20:18:33

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, PRODUCT: AMANTADINE HYDROCHLORIDE, PRODUCTSYNONYM: SYMMETREL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 08:41:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:41:33
Data point term sent to Coder	System	29 Mar 2021 19:08:44
User entered 'symmetrel'	Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'anxiety'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:58
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM). Signature has been broken.	(b) (4), (b) (6) Cassandra Zehenny (b) (4) Cassandra Zehenny (b) (4)	07 Apr 2021 11:56:58 06 Apr 2021 15:08:37 06 Apr 2021 15:08:24
User entered '200' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	06 Apr 2021 15:08:24
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) sharon frey (b) (4)	06 Apr 2021 11:29:33 30 Mar 2021 16:33:41
User entered 'I'	Stanley Doublin (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered '25 Mar 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:33:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 19:08:21

US3552473

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:17:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:45:08
User entered 'Yes (Y)'	Heather Douds (b) (4)	08 Dec 2020 13:42:26
	(b) (4)	

US3552473

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:08:54
User entered '25 Nov 2020'	Heather Douds (b) (4)	08 Dec 2020 13:42:52
	(b) (4)	

US3552473

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:08:54
User entered 'Incision and drainage of perirectal abscess'	Heather Douds (b) (4) (b) (4)	08 Dec 2020 13:42:52

US3552473

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:08:54
User entered 'Adverse Event (AE)'	Heather Douds (b) (4)	08 Dec 2020 13:42:52
	(b) (4)	

US3552473

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:08:54
User entered empty.	Heather Douds (b) (4)	08 Dec 2020 13:42:52
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'USA-US089-2020-MRNA-1273-P301000015'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'sharon'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'frey'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	10 Dec 2020 17:35:00
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'Saint Louis'	(b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'MO'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '63104'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'US'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '4'	(b) (4)	16 Dec 2020 13:37:21
User entered '3'	System	10 Dec 2020 17:35:12
User entered '2'	System	08 Dec 2020 15:02:37
User entered '1'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'USA-US089-2020-MRNA-1273-P301000015'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'sharon'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'frey'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'Saint Louis'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'MO'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '63104'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'US'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '4'	(b) (4) System	16 Dec 2020 13:37:21
User entered '3'	System	10 Dec 2020 17:35:12
User entered '2'	System	08 Dec 2020 15:02:37
User entered '1'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:16:50
User entered '05/Dec/2020 13:38'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:17:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'l'		05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'USA-US089-2020-MRNA-1273-P301000015'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'sharon'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'frey'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'Saint Louis'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'MO'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '63104'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'US'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '4'	(b) (4) System	16 Dec 2020 13:37:21
User entered '3'	System	10 Dec 2020 17:35:12
User entered '2'	System	08 Dec 2020 15:02:37
User entered '1'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:16:50
User entered '08/Dec/2020 10:02'	System	08 Dec 2020 15:02:37

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:17:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	10 Dec 2020 17:35:00
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:16:50
User entered 'l'		08 Dec 2020 15:02:37

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'USA-US089-2020-MRNA-1273-P301000015'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'sharon'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'frey'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'Saint Louis'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'MO'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '63104'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'US'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '4'	(b) (4) System	16 Dec 2020 13:37:21
User entered '3'	System	10 Dec 2020 17:35:12
User entered '2'	System	08 Dec 2020 15:02:37
User entered '1'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:52:32
User entered '10/Dec/2020 17:35'	System	10 Dec 2020 17:35:12

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:17:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	21 Dec 2020 20:52:33
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 13:37:15
User entered 'l'		10 Dec 2020 17:35:12

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'USA-US089-2020-MRNA-1273-P301000015'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'Yes (Y)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'No (N)'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'sharon'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'frey'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'Saint Louis'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:38:20
User entered 'MO'	System	05 Dec 2020 18:37:39

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:35:00
DataPoint Verified.		09 Dec 2020 20:16:50
Un-reviewed for Safety.	System	08 Dec 2020 15:02:37
User entered empty.	System	08 Dec 2020 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered '63104'	Heather Douds (b) (4)	08 Dec 2020 13:42:07
	(b) (4)	

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:16:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:02:29
User entered 'US'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
User entered '4'	(b) (4) System	16 Dec 2020 13:37:21
User entered '3'	System	10 Dec 2020 17:35:12
User entered '2'	System	08 Dec 2020 15:02:37
User entered '1'	System	05 Dec 2020 18:38:34

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:52:41
User entered '16/Dec/2020 13:37'	System	16 Dec 2020 13:37:21

US3552473

Folder: SAE USA-US089-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:30:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:52:42
User entered 'l'		16 Dec 2020 13:37:21