

US3552240 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:12:45

All time stamps listed in this document are displayed in GMT

US3552240

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 18:22:46

Generated On: 10 Jun 2021 08:12:45

Participant ID

US3552240

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

US3552240

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	39
Age Units	YEARS
Age (Derived)	39
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3552240

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3552240

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3552240

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Were any significant conditions reported?

Yes ☒

No ☐

US3552240

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552240

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	BILATERAL SCIATICA
Start date (dd MMM yyyy)	01 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552240

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3552240

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 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

US3552240

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	CONCUSSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3552240

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	LEFT WRIST FRACTURE
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

US3552240

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	VASECTOMY
Start date (dd MMM yyyy)	20 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	20 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

US3552240

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	HEADACHES
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)	

US3552240

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Condition	ECZEMA
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)	_____

US3552240

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 13:00
Height (xxx.x)	77.5 in
Weight (xxx.x)	279 lb
BMI (xxx.x)	32.72734 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)	

US3552240

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

US3552240

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

DOES ALL GROCERY
SHOPPING, VISITS WITH HIS
IN-LAWS, TAKES KIDS TO
PARK, IN 3 WEEKS - 2 YEAR
OLD WILL GO TO DAYCARE,
SWIMS 2 TIMES A WEEK AT
YMCA (INDOOR POOL),
SOCIALIZES ON BACK PORCH
WITH FRIENDS

Location and Living Circumstances Risk (check all that apply)

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

US3552240

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

What was the date of randomization? (dd MMM yyyy) 29 AUG 2020

What was the participant's randomization number? 110033

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 ☒

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Height	ND - Not Done
Weight	ND - Not Done

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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)	29 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 13:00
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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)	29 AUG 2020
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 15:01
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3552240

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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.

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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) 29 AUG 2020

What was the treatment time? (00:00-23:59) 14:31 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 14:31

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

US3552240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 AUG 2020
Collection time (00:00-23:59)	14:00 (24 HR)
Collection date and time (derived)	29 AUG 2020 14:00

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	29 AUG 2020 14:05
Nasopharyngeal Swab 2	No		

US3552240

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 14:59

PC Open Date & Time

29 AUG 2020 14:51

PC Close Date & Time

29 AUG 2020 17:21

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

98.0 °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	29 AUG 2020 20:04
PC Open Date & Time	29 AUG 2020 18:16
PC Close Date & Time	30 AUG 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

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

97.5 °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

30 AUG 2020 20:00

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

31 AUG 2020 20:00

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

01 SEP 2020 20:00

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:04

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:20

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

04 SEP 2020 20:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

29 AUG 2020 15:01

PC Open Date & Time

29 AUG 2020 14:51

PC Close Date & Time

29 AUG 2020 17:21

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

29 AUG 2020 20:07

PC Open Date & Time

29 AUG 2020 18:16

PC Close Date & Time

30 AUG 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

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

30 AUG 2020 20:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

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

31 AUG 2020 20:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

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

01 SEP 2020 20:01

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

02 SEP 2020 20:07

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

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

03 SEP 2020 20:21

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

04 SEP 2020 20:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 14:51

PC Close Date & Time

29 AUG 2020 17:21

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 20:03
PC Open Date & Time	29 AUG 2020 18:16
PC Close Date & Time	30 AUG 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2607

EAB) (1725)

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 2607

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

59 of 2607

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 20:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

61 of 2607

EAB) (1725)

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

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

63 of 2607

EAB) (1725)

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:21
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

65 of 2607

EAB) (1725)

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3552240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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)	01 OCT 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 11:40
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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)	01 OCT 2020
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 13:06
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3552240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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) 01 OCT 2020

What was the treatment time? (00:00-23:59) 12:36 (24 HR)

Treatment Date and Time (derived) 01 OCT 2020 12:36

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

US3552240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	12:08 (24 HR)
Collection date and time (derived)	01 OCT 2020 12:08

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:11	01 OCT 2020 12:11
Nasopharyngeal Swab 2	No		

US3552240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

98.0 °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

01 OCT 2020 13:04

PC Open Date & Time

01 OCT 2020 12:56

PC Close Date & Time

01 OCT 2020 15:26

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 98.4 °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	01 OCT 2020 20:18
PC Open Date & Time	01 OCT 2020 16:21
PC Close Date & Time	02 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

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

97.5 °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

03 OCT 2020 04:49

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

03 OCT 2020 21:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

05 OCT 2020 04:10

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 19:20

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

07 OCT 2020 09:35

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	07 OCT 2020 14:50
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 20:19

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

01 OCT 2020 13:05

PC Open Date & Time

01 OCT 2020 12:56

PC Close Date & Time

01 OCT 2020 15:26

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

01 OCT 2020 20:14

PC Open Date & Time

01 OCT 2020 16:21

PC Close Date & Time

02 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

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

03 OCT 2020 04:50

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

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

03 OCT 2020 21:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

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

05 OCT 2020 04:10

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

05 OCT 2020 19:20

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

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

07 OCT 2020 09:35

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

07 OCT 2020 14:51

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 13:05
PC Open Date & Time	01 OCT 2020 12:56
PC Close Date & Time	01 OCT 2020 15:26

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 20:15
PC Open Date & Time	01 OCT 2020 16:21
PC Close Date & Time	02 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 2607

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 04:51
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

104 of 2607

EAB) (1725)

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 21:33
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

106 of 2607

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 04:10
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

108 of 2607

EAB) (1725)

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:21
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

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

EAB) (1725)

110 of 2607

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 09:35
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

112 of 2607

EAB) (1725)

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 14:52
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 08 OCT 2020 20:19

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3552240

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 20:19
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3552240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	VISIT3

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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) _____

US3552240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

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.

US3552240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	11:59 (24 HR)
Collection date and time (derived)	30 OCT 2020 11:59

US3552240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:08

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 15:02:19

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 07:00:11

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

15 NOV 2020 19:55:55

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 13:09:42

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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	30 NOV 2020 19:55:25
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 19:55:23

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 19:55:25

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

21 DEC 2020 19:55:26

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 21:48:56

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

04 JAN 2021 19:55:25

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

11 JAN 2021 19:55:25

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

18 JAN 2021 19:56:06

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 19:55:29

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 20:09:35

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

08 FEB 2021 19:57:15

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

15 FEB 2021 19:55:27

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 19:55:27

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 19:55:53

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 20:24:39

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 20:09:40

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	22 MAR 2021 20:10:18
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

29 MAR 2021 19:58:42

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 21:10:39

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 20:09:51

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 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	19 APR 2021 20:14:58
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Date and time of submission

29 APR 2021 08:53:55

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	28 JUN 2021 00:01
Patient Cloud Close Date & Time	02 JUL 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	05 JUL 2021 00:01
Patient Cloud Close Date & Time	09 JUL 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	26 JUL 2021 00:01
Patient Cloud Close Date & Time	30 JUL 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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 <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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

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

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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"/>

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3552240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:12:45

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		01 MAR 2021 19:56:24

US3552240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 27 Feb 2021 17:54:32

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 27 Feb 2021 17:54:32

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 15:31:51

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:27:02

Generated On: 10 Jun 2021 08:12:45

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) _____

US3552240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 15:31:51

Generated On: 10 Jun 2021 08:12:45

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.

US3552240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 15:31:51

Generated On: 10 Jun 2021 08:12:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	11:37 (24 HR)
Collection date and time (derived)	18 MAR 2021 11:37

US3552240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:31:51

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 18:23:06

Generated On: 10 Jun 2021 08:12:45

Date of Contact	14 JAN 2021
Time of Contact	10:21
Date and Time of Contact (derived)	14 JAN 2021 10:21
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

329 of 2607

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

333 of 2607

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

337 of 2607

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 2607

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	96.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 2607

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97 F
-------------	------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

349 of 2607

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 18:22:47

Generated On: 10 Jun 2021 08:12:45

Date of Visit 15 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 15 JAN 2021

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 21 Feb 2021 18:23:06

Generated On: 10 Jun 2021 08:12:45

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 18:23:06

Generated On: 10 Jun 2021 08:12:45

Date of Contact	14 JAN 2021
Time of Contact	10:21
Date and Time of Contact (derived)	14 JAN 2021 10:21
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 18:23:06

Generated On: 10 Jun 2021 08:12:45

Date of Visit 15 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 15 JAN 2021

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒
No ☐

If yes, provide lab information below

Lab/ Institution Test Performed SAINT LOUIS UNIVERSITY'S
VACCINE DEVELOPMENT
CENTER

CLIA Certified? Yes ☒
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3552240

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 12:15
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552240

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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.

US3552240

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 JAN 2021

US3552240

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

Visit date (dd MMM yyyy)	07 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
------------	---------------

US3552240

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:31:51

Generated On: 10 Jun 2021 08:12:45

Date of updated informed consent (<i>dd MMM yyyy</i>)	07 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>)	07 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

US3552240

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Height	77.5 in
Weight	273.6 lb
BMI (xxx.x)	32.09391

US3552240

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Height	77.5 in
Weight	273.6 lb
BMI (xxx.x)	32.09391
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)	07 JAN 2021
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	07 JAN 2021 10:32
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3552240

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Height	77.5 in
Weight	273.6 lb
BMI (xxx.x)	32.09391
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)	07 JAN 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	07 JAN 2021 10:55
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3552240

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 JAN 2021

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

US3552240

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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) 07 JAN 2021

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 07 JAN 2021 10:55

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

US3552240

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 JAN 2021
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	07 JAN 2021 10:15

US3552240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 JAN 2021
Collection time (00:00 - 23:59)	10:20
Collection Date and Time (derived)	07 JAN 2021 10:20

US3552240

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3552240

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3552240

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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)	04 FEB 2021
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 11:29
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	12:21 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 12:21
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3552240

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 FEB 2021

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

US3552240

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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) 04 FEB 2021

What was the treatment time? (00:00-23:59) 11:51 (24 HR)

Treatment Date and Time (derived) 04 FEB 2021 11:51

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

US3552240

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:23:07

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 27 Feb 2021 17:54:32

Generated On: 10 Jun 2021 08:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552240

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 15:31:50

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 15:31:50

Generated On: 10 Jun 2021 08:12:45

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) _____

US3552240

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 15:31:50

Generated On: 10 Jun 2021 08:12:45

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.

US3552240

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 15:31:50

Generated On: 10 Jun 2021 08:12:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	11:37 (24 HR)
Collection date and time (derived)	18 MAR 2021 11:37

US3552240

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 18:22:46

Generated On: 10 Jun 2021 08:12:45

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

AEID

Adverse event

COUGH

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

14 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

14 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003
EAB) (1725)

386 of 2607

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

AEID

Adverse event

RHINORRHEA

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

11 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

14 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 2607

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

AEID

Adverse event

FATIGUE

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

16 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

22 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003
EAB) (1725)

390 of 2607

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

AEID

Adverse event

NASAL CONGESTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

392 of 2607

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

AEID	USA-US089-2021-MRNA-1273-P30 1000006
Adverse event	HASHIMOTO'S DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 2607

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

SUBJECT HAD ROUTINE LABS
THROUGH PCP AND FOUND TO
HAVE A HIGH THYROID
STIMULATING HORMONE WITH
A RESULT OF 8.613 ON 02FEB.
DEVELOPED SYMPTOMS OF
HAIR LOSS AND JOINT ACHES
AND THEN DIAGNOSED WITH
HASHIMOTO'S DISEASE.
PRESCRIBED SYNTHROID 75
MCG DAILY.

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)	
--	--

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

AEID	
Adverse event	THYROID NODULES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2607

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

AEID	
Adverse event	LEFT PERONEAL TENDONITIS
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)	20 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 2607

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 18:22:47

Generated On: 10 Jun 2021 08:12:45

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

Yes ☒

No ☐

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

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	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 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication LOW BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	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 2012	
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"/>

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication HEALTH

Dose per administration 3000

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)

406 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	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 JUN 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"/>

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication LEFT ANKLE SPRAIN

Dose per administration 30

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)

408 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	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)		03 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 AUG 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"/>

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify CC

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)

410 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication EXCEDRIN ES
[ACETAMINOPHEN 250MG,
ASPIRIN 250 MG, CAFFEINE 65
MG]

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	Transdermal	<input type="checkbox"/>
	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)		07 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)		07 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication MOMETASONE

Prophylaxis Yes ☐
No ☒

Indication ECZEMA

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	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)		20 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)		22 OCT 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"/>

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HASHIMOTO'S DISEASE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	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)	03 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
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"/>

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HASHIMOTO'S DISEASE

Dose per administration 75

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)

418 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

	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)	19 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"/>

US3552240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3552240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Mar 2021 13:57:19

Generated On: 10 Jun 2021 08:12:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 MAR 2021	NEEDLE ASPIRATION OF THYROID NODULE	Adverse Event	

US3552240

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:12:45

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

US3552240

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:12:45

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 ☐

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 18:02:43

Generated On: 10 Jun 2021 08:12:45

SAEID	USA-US089-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	3

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 18:02:43

Generated On: 10 Jun 2021 08:12:45

SAEID	USA-US089-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	25/MAR/2021 08:25
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

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 18:02:43

Generated On: 10 Jun 2021 08:12:45

SAEID	USA-US089-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	07/APR/2021 09:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 18:02:43

Generated On: 10 Jun 2021 08:12:45

SAEID	USA-US089-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 06:25
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

US3552240 (Prod: Saint Louis University)

US3552240

Form: Participant Creation

Generated On: 10 Jun 2021 08:12:45

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'US3552240'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:35:41

US3552240

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:34:49

US3552240

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:35:42

US3552240

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:34:49

US3552240

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'SCRN'	System	31 Aug 2020 12:34:49

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered (b) (6) 1980'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:35:43

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '39'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'YEARS'	System	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '39'	System	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Male (M)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:35:20

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Aug 2020'	System	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2020'	System	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:07:30

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:35:42

US3552240

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'l'	System	29 Aug 2020 19:07:38

US3552240

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:07:38

US3552240

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:12:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:37:06

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:38:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:38:53
Data point term sent to Coder	System	31 Aug 2020 12:38:07
User entered 'seasonal allergies'	Stanley Doublin (b) (4)	31 Aug 2020 12:37:25
	(b) (4)	

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2019'	System	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2019'	System	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:37:25

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament sprain, LLT: Ankle sprain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:39:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:39:45
Data point term sent to Coder	System	31 Aug 2020 12:39:08
User entered 'Left ankle sprain'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un Jul 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un Jul 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jul 2020'	System	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2020'	System	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jul 2020'	System	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2020'	System	31 Aug 2020 12:38:11

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Mueller-Weiss syndrome, LLT: Mueller-Weiss syndrome - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 16:02:51
Data point term sent to Coder	(b) (4)	
User entered 'muller weiss disease'	System	29 Sep 2020 16:02:51
	Stanley Dublin (b) (4)	31 Aug 2020 12:39:08
	(b) (4)	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2018'	System	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2018'	System	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:39:03

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 12:40:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 12:40:53
Data point term sent to Coder	System	31 Aug 2020 12:40:09
User entered 'lower back pain'	Stanley Doublin (b) (4)	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2007'	System	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2007'	System	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:39:22

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:41:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:41:59
Data point term sent to Coder	System	31 Aug 2020 12:41:12
User entered 'bilateral sciatica'	Stanley Doublin (b) (4)	31 Aug 2020 12:40:54
	(b) (4)	

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '01 Nov 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Nov 2018'	System	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2018'	System	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:40:54

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 15:44:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:44:33
Data point term sent to Coder	System	31 Aug 2020 12:41:11
User entered 'tinnitus bilateral'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2018'	System	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2018'	System	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	31 Aug 2020 12:41:10

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 12:42:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 12:42:47
Data point term sent to Coder	System	31 Aug 2020 12:42:12
User entered 'appendectomy'	Stanley Doublin (b) (4)	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 1999'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 1999'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 1999'	System	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '1999'	System	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 1999'	System	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '1999'	System	31 Aug 2020 12:41:39

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:43:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:43:52
Data point term sent to Coder	System	31 Aug 2020 12:43:13
User entered 'BASAL CELL CARCINOMA' reason for change: Data Entry Error	Stanley Doublin (b) (4)	31 Aug 2020 12:42:54
User entered 'basal cell careinoma'	(b) (4) Stanley Doublin (b) (4)	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2013'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 12:42:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 12:42:31
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	31 Aug 2020 12:42:31
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 12:42:14
User entered empty.	Stanley Dublin (b) (4)	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2013'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2013'	System	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2013'	System	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2013'	System	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2013'	System	31 Aug 2020 12:42:14

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:44:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:44:47
Data point term sent to Coder	System	31 Aug 2020 12:44:14
User entered 'basal cell carcinoma'	Stanley Doublin (b) (4)	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2018'	System	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2018'	System	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2018'	System	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2018'	System	31 Aug 2020 12:43:51

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Concussion, LLT: Concussion - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:46:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:46:51
Data point term sent to Coder	System	31 Aug 2020 12:45:14
User entered 'concussion'	Stanley Doublin (b) (4)	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2000'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 12:44:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 12:44:32
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	31 Aug 2020 12:44:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 12:44:20
User entered empty.	System	31 Aug 2020 12:44:20
	Stanley Dublin (b) (4)	31 Aug 2020 12:44:20
	(b) (4)	

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2000'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2000'	System	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2000'	System	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2000'	System	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2000'	System	31 Aug 2020 12:44:20

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Wrist fracture - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:46:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:46:51
Data point term sent to Coder	System	31 Aug 2020 12:45:14
User entered 'left wrist fracture'	Stanley Doublin (b) (4)	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 1993'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
	System	31 Aug 2020 12:45:12
User entered 'un UNK 1993' reason for change: Data Entry Error	Stanley Doublin (b) (4)	31 Aug 2020 12:45:12
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 12:45:04
User entered 'in 1993' (non-conformant).	Stanley Doublin (b) (4)	31 Aug 2020 12:45:04
	(b) (4)	

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 1993'	System	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '1993'	System	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 1993'	System	31 Aug 2020 12:45:12
User entered empty.	System	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '1993'	System	31 Aug 2020 12:45:12
User entered empty.	System	31 Aug 2020 12:45:04

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 12:47:44
Data point term sent to Coder	System	31 Aug 2020 12:46:15
User entered 'vasectomy'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '20 Dec 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '20 Dec 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Dec 2019'	System	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2019'	System	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Dec 2019'	System	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2019'	System	31 Aug 2020 12:45:43

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:29:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 15:29:32
Data point term sent to Coder	System	11 Nov 2020 15:13:29
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 15:12:33
User entered 'HEADACHES' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 15:12:33
Data point term sent to Coder	System	11 Nov 2020 15:12:28
User closed query 'CDM-Coding:For coding purpose, Please update this term by providing a combined diagnosis, alternatively please split and record as 1)DEHYDRATION 2 HEADACHES' (Site from System).	System	11 Nov 2020 15:12:27
Query 'CDM-Coding:For coding purpose, Please update this term by providing a combined diagnosis, alternatively please split and record as 1)DEHYDRATION 2 HEADACHES' answered with 'updated appropriately' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 15:12:27
User opened query 'CDM-Coding:For coding purpose, Please update this term by providing a combined diagnosis, alternatively please split and record as 1)DEHYDRATION 2 HEADACHES' (Site from System).	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:30:45
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 11:11:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 11:11:19
Data point term sent to Coder	System	08 Oct 2020 21:41:16
User entered 'Dehydration headaches'	Cassandra Zehenny (b) (4) (b) (4)	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4)	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	08 Oct 2020 21:40:45

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 16:27:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 16:27:35
Data point term sent to Coder	System	22 Oct 2020 16:26:44
User entered 'eczema'	Mikayla Frye (b) (4)	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'un UNK 2010'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'Jan 2010'	System	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '2010'	System	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered empty.	System	22 Oct 2020 16:25:56

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 12:46:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 12:46:30
User entered '13:00' reason for change: Data Entry Error	Stanley Dublin (b) (4)	31 Aug 2020 12:46:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 12:46:22
User entered empty.	Stanley Dublin (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '29 Aug 2020 13:00'	System	31 Aug 2020 12:46:30
User entered empty.	System	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '77.5' in	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:46:22
DataPoint set to visible.	(b) (4) System	29 Aug 2020 19:07:38

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '279' lb	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:46:22
DataPoint set to visible.	(b) (4) System	29 Aug 2020 19:07:38

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered '32.72734'	System	31 Aug 2020 12:46:22
DataPoint set to visible.	System	29 Aug 2020 19:07:38

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'kg/m2'	System	31 Aug 2020 12:46:22
DataPoint set to visible.	System	29 Aug 2020 19:07:38

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'bpm'	System	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'breaths/min'	System	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'mmHg'	System	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User entered 'mmHg'	System	31 Aug 2020 12:46:22

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51

US3552240

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51

US3552240

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:41

US3552240

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:46:41

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

[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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

[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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'does all grocery shopping, visits with his in-laws, takes kids to park, in 3 weeks - 2 year old will go to daycare, swims 2 times a week at YMCA (indoor pool), socializes on back porch with friends'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

[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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:15

US3552240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:38

US3552240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:38

US3552240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:38

US3552240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'VISIT1'	System	31 Aug 2020 12:49:38

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 19:10:32

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '110033'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 19:10:32

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 19:10:32

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:48

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:48

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:48

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:48

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:49:48

US3552240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 17:40:26
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:38:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:38:29

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '13:00'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '29 Aug 2020 13:00'	System	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '97.7' F	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '64'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'bpm'	System	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '14'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'breaths/min'	System	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '129'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'mmHg'	System	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '80'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'mmHg'	System	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:50:28

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '15:01'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '29 Aug 2020 15:01'	System	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 10:01:30
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:47:00
answered with 'NCS' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:11:16
User entered '96.5' F	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '56'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'bpm'	System	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '16'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'breaths/min'	System	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '132'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'mmHg'	System	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '78'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'mmHg'	System	31 Aug 2020 12:51:06

US3552240

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:12

US3552240

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:12

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '14:31'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '29 Aug 2020 14:31'	System	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'ONCE'	System	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 19:34:53

US3552240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:29

US3552240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:29

US3552240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '14:00'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:29

US3552240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '29 Aug 2020 14:00'	System	31 Aug 2020 12:51:29

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '14:05'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '29 Aug 2020 14:05'	System	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered empty.	System	31 Aug 2020 12:51:47

US3552240

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Joan Siegner (b) (4)	05 Sep 2020 17:01:43

US3552240

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'I'	System	05 Sep 2020 17:01:43

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T14:58:44', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '07e5e8da-0b81-435a-b38a-8cfc7adae5fc' User entered 'Yes (Y)'	System	29 Aug 2020 19:59:15
	System	29 Aug 2020 19:59:15

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T14:58:50', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '07e5e8da-0b81-435a-b38a-8cfc7adae5fc' User entered '96.5'	System	29 Aug 2020 19:59:15
	System	29 Aug 2020 19:59:15

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T14:59:09', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '07e5e8da-0b81-435a-b38a-8cfc7adae5fc'	System	29 Aug 2020 19:59:15
User entered 'No (N)'	System	29 Aug 2020 19:59:15

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T14:59:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '07e5e8da-0b81-435a-b38a-8cfc7adae5fc' User entered '29 Aug 2020 14:59'	System	29 Aug 2020 19:59:15
	System	29 Aug 2020 19:59:15

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 14:51'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 17:21'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:04:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6c30f374-e41d-4cff-acca-aa4d9738bb1f' User entered 'Yes (Y)'	System	30 Aug 2020 01:04:59
	System	30 Aug 2020 01:04:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:04:30', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6c30f374-e41d-4cff-acca-aa4d9738bb1f' User entered '98.0'	System	30 Aug 2020 01:04:59
	System	30 Aug 2020 01:04:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:04:36', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6c30f374-e41d-4cff-acca-aa4d9738bb1f' User entered 'No (N)'	System	30 Aug 2020 01:04:59
	System	30 Aug 2020 01:04:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:04:56', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6c30f374-e41d-4cff-acca-aa4d9738bb1f' User entered '29 Aug 2020 20:04'	System	30 Aug 2020 01:04:59
	System	30 Aug 2020 01:04:59

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 18:16'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 2'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:00:33', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a47fcac7-fe83-452e-bc79-acb87982059b'	System	31 Aug 2020 01:01:04
User entered 'Yes (Y)'	System	31 Aug 2020 01:01:04

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:00:42', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a47fcac7-fe83-452e-bc79-acb87982059b' User entered '97.5'	System	31 Aug 2020 01:01:04
	System	31 Aug 2020 01:01:04

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:00:52', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a47fcac7-fe83-452e-bc79-acb87982059b'	System	31 Aug 2020 01:01:04
User entered 'No (N)'	System	31 Aug 2020 01:01:04

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:00:59', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a47fcac7-fe83-452e-bc79-aeb87982059b'	System	31 Aug 2020 01:01:04
User entered '30 Aug 2020 20:00'	System	31 Aug 2020 01:01:04

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 3'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:00:18', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '842fd00b-8504-449d-8f2e-00e47f22cf85'	System	01 Sep 2020 01:00:38
User entered 'Yes (Y)'	System	01 Sep 2020 01:00:38

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:00:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '842fd00b-8504-449d-8f2e-00e47f22cf85' User entered '96.5'	System	01 Sep 2020 01:00:38
	System	01 Sep 2020 01:00:38

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:00:29', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '842fd00b-8504-449d-8f2e-00e47f22cf85'	System	01 Sep 2020 01:00:38
User entered 'No (N)'	System	01 Sep 2020 01:00:38

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:00:31', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '842fd00b-8504-449d-8f2e-00e47f22cf85'	System	01 Sep 2020 01:00:38
User entered '31 Aug 2020 20:00'	System	01 Sep 2020 01:00:38

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 4'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:00:30', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1fe8f607-cc3f-49ec-8816-334f4553057e'	System	02 Sep 2020 01:00:42
User entered 'Yes (Y)'	System	02 Sep 2020 01:00:42

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:00:33', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1fe8f607-cc3f-49ec-8816-334f4553057e' User entered '97.5'	System	02 Sep 2020 01:00:42
	System	02 Sep 2020 01:00:42

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:00:36', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1fe8f607-cc3f-49ec-8816-334f4553057e'	System	02 Sep 2020 01:00:42
User entered 'No (N)'	System	02 Sep 2020 01:00:42

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:00:39', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1fe8f607-cc3f-49ec-8816-334f4553057e'	System	02 Sep 2020 01:00:42
User entered '01 Sep 2020 20:00'	System	02 Sep 2020 01:00:42

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 5'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:04:30', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5e042aff-a192-4c5a-9c44-2de15ae31531' User entered 'Yes (Y)'	System	03 Sep 2020 01:04:43
	System	03 Sep 2020 01:04:43

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:04:34', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5e042aff-a192-4c5a-9c44-2de15ae31531' User entered '97.1'	System	03 Sep 2020 01:04:43
	System	03 Sep 2020 01:04:43

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:04:37', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5e042aff-a192-4c5a-9c44-2de15ae31531' User entered 'No (N)'	System	03 Sep 2020 01:04:43
	System	03 Sep 2020 01:04:43

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:04:40', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5e042aff-a192-4c5a-9c44-2de15ae31531' User entered '02 Sep 2020 20:04'	System	03 Sep 2020 01:04:43
	System	03 Sep 2020 01:04:43

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 6'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:30', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1d015b95-6571-42ec-9646-4dcbcc391649' User entered 'Yes (Y)'	System	04 Sep 2020 01:20:45
	System	04 Sep 2020 01:20:45

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:38', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1d015b95-6571-42ec-9646-4dcbcc391649' User entered '97.6'	System	04 Sep 2020 01:20:45
	System	04 Sep 2020 01:20:45

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:40', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1d015b95-6571-42ec-9646-4dcbcc391649' User entered 'No (N)'	System	04 Sep 2020 01:20:45
	System	04 Sep 2020 01:20:45

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:43', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1d015b95-6571-42ec-9646-4dcbcc391649' User entered '03 Sep 2020 20:20'	System	04 Sep 2020 01:20:45
	System	04 Sep 2020 01:20:45

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 7'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:00:42', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1b010f44-9c44-4b64-a476-2a4c102a4941' User entered 'Yes (Y)'	System	05 Sep 2020 01:02:11
	System	05 Sep 2020 01:02:11

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:00:47', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1b010f44-9c44-4b64-a476-2a4c102a4941' User entered '97.1'	System	05 Sep 2020 01:02:11
	System	05 Sep 2020 01:02:11

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:00:50', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1b010f44-9c44-4b64-a476-2a4c102a4941' User entered 'No (N)'	System	05 Sep 2020 01:02:11
	System	05 Sep 2020 01:02:11

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:04', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1b010f44-9c44-4b64-a476-2a4c102a4941' User entered '04 Sep 2020 20:02'	System	05 Sep 2020 01:02:11
	System	05 Sep 2020 01:02:11

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T15:01:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '294e9d3e-2d78-4229-ad76-a69c6b4af535'	System	29 Aug 2020 20:01:46
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 20:01:46

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T15:01:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '294e9d3e-2d78-4229-ad76-a69c6b4af535'	System	29 Aug 2020 20:01:46
User entered 'No (N)'	System	29 Aug 2020 20:01:46

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T15:01:35', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '294e9d3e-2d78-4229-ad76-a69c6b4af535'	System	29 Aug 2020 20:01:46
User entered 'No (N)'	System	29 Aug 2020 20:01:46

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T15:01:40', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '294e9d3e-2d78-4229-ad76-a69c6b4af535'	System	29 Aug 2020 20:01:46
User entered 'None (1)'	System	29 Aug 2020 20:01:46

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T15:01:42', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '294e9d3e-2d78-4229-ad76-a69c6b4af535' User entered '29 Aug 2020 15:01'	System	29 Aug 2020 20:01:46
	System	29 Aug 2020 20:01:46

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 14:51'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 17:21'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:05:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9bce8c29-9a29-4521-a8ae-23253d796ff9'	System	30 Aug 2020 01:07:56
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 01:07:56

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:05:32', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9bce8c29-9a29-4521-a8ae-23253d796ff9'	System	30 Aug 2020 01:07:56
User entered 'No (N)'	System	30 Aug 2020 01:07:56

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:05:56', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9bce8c29-9a29-4521-a8ae-23253d796ff9'	System	30 Aug 2020 01:07:56
User entered 'No (N)'	System	30 Aug 2020 01:07:56

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:07:50', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9bce8c29-9a29-4521-a8ae-23253d796ff9'	System	30 Aug 2020 01:07:56
User entered 'None (1)'	System	30 Aug 2020 01:07:56

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:07:55', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9bce8c29-9a29-4521-a8ae-23253d796ff9' User entered '29 Aug 2020 20:07'	System	30 Aug 2020 01:07:56
	System	30 Aug 2020 01:07:56

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 18:16'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 2'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:01:16', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'aaaf057a-cc7c-4429-8255-222fa0b6d695'	System	31 Aug 2020 01:02:52
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 01:02:52

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:02:06', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'aaaf057a-cc7c-4429-8255-222fa0b6d695'	System	31 Aug 2020 01:02:52
User entered 'No (N)'	System	31 Aug 2020 01:02:52

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:02:27', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'aaaf057a-cc7c-4429-8255-222fa0b6d695'	System	31 Aug 2020 01:02:52
User entered 'No (N)'	System	31 Aug 2020 01:02:52

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:02:46', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'aaaf057a-cc7c-4429-8255-222fa0b6d695'	System	31 Aug 2020 01:02:52
User entered 'None (1)'	System	31 Aug 2020 01:02:52

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:02:49', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'aaaf057a-cc7c-4429-8255-222fa0b6d695'	System	31 Aug 2020 01:02:52
User entered '30 Aug 2020 20:02'	System	31 Aug 2020 01:02:52

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 3'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:00:40', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'babb4181-0ec1-4c75-a34e-697b117a2f8a' User entered 'None (1)'	System	01 Sep 2020 01:01:18
	System	01 Sep 2020 01:01:18

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:00:44', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'babb4181-0ec1-4c75-a34e-697b117a2f8a' User entered 'No (N)'	System	01 Sep 2020 01:01:18
	System	01 Sep 2020 01:01:18

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:00:46', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'babb4181-0ec1-4c75-a34e-697b117a2f8a' User entered 'No (N)'	System	01 Sep 2020 01:01:18
	System	01 Sep 2020 01:01:18

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:01:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'babb4181-0ec1-4c75-a34e-697b117a2f8a' User entered 'None (1)'	System	01 Sep 2020 01:01:18
	System	01 Sep 2020 01:01:18

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:01:16', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'babb4181-0ec1-4c75-a34e-697b117a2f8a' User entered '31 Aug 2020 20:01'	System	01 Sep 2020 01:01:18
	System	01 Sep 2020 01:01:18

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 4'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:00:44', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '25dd1b9b-22cd-403b-a143-14353cc90487'	System	02 Sep 2020 01:01:17
User entered 'None (1)'	System	02 Sep 2020 01:01:17

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:05', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '25dd1b9b-22cd-403b-a143-14353cc90487'	System	02 Sep 2020 01:01:17
User entered 'No (N)'	System	02 Sep 2020 01:01:17

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:08', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '25dd1b9b-22cd-403b-a143-14353cc90487'	System	02 Sep 2020 01:01:17
User entered 'No (N)'	System	02 Sep 2020 01:01:17

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:11', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '25dd1b9b-22cd-403b-a143-14353cc90487'	System	02 Sep 2020 01:01:17
User entered 'None (1)'	System	02 Sep 2020 01:01:17

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '25dd1b9b-22cd-403b-a143-14353cc90487' User entered '01 Sep 2020 20:01'	System	02 Sep 2020 01:01:17
	System	02 Sep 2020 01:01:17

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 5'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c2e9a6ff-4e07-44ce-92bf-496953d75620'	System	03 Sep 2020 01:07:04
User entered 'None (1)'	System	03 Sep 2020 01:07:04

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:54', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c2e9a6ff-4e07-44ce-92bf-496953d75620'	System	03 Sep 2020 01:07:04
User entered 'No (N)'	System	03 Sep 2020 01:07:04

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:56', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c2e9a6ff-4e07-44ce-92bf-496953d75620'	System	03 Sep 2020 01:07:04
User entered 'No (N)'	System	03 Sep 2020 01:07:04

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:58', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c2e9a6ff-4e07-44ce-92bf-496953d75620'	System	03 Sep 2020 01:07:04
User entered 'None (1)'	System	03 Sep 2020 01:07:04

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:07:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c2e9a6ff-4e07-44ce-92bf-496953d75620' User entered '02 Sep 2020 20:07'	System	03 Sep 2020 01:07:04
	System	03 Sep 2020 01:07:04

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 6'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:21:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b389991-b080-4c5b-8e05-26622f7a371d'	System	04 Sep 2020 01:21:47
User entered 'None (1)'	System	04 Sep 2020 01:21:47

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:21:29', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b389991-b080-4c5b-8e05-26622f7a371d' User entered 'No (N)'	System	04 Sep 2020 01:21:47
	System	04 Sep 2020 01:21:47

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:21:38', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b389991-b080-4c5b-8e05-26622f7a371d' User entered 'No (N)'	System	04 Sep 2020 01:21:47
	System	04 Sep 2020 01:21:47

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:21:40', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b389991-b080-4c5b-8e05-26622f7a371d'	System	04 Sep 2020 01:21:47
User entered 'None (1)'	System	04 Sep 2020 01:21:47

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:21:43', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b389991-b080-4c5b-8e05-26622f7a371d' User entered '03 Sep 2020 20:21'	System	04 Sep 2020 01:21:47
	System	04 Sep 2020 01:21:47

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 7'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:08', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e6b0ebf8-1561-4a5d-97f6-a18231508834'	System	05 Sep 2020 01:02:24
User entered 'None (1)'	System	05 Sep 2020 01:02:24

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:10', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e6b0ebf8-1561-4a5d-97f6-a18231508834' User entered 'No (N)'	System	05 Sep 2020 01:02:24
	System	05 Sep 2020 01:02:24

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e6b0ebf8-1561-4a5d-97f6-a18231508834' User entered 'No (N)'	System	05 Sep 2020 01:02:24
	System	05 Sep 2020 01:02:24

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:15', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e6b0ebf8-1561-4a5d-97f6-a18231508834'	System	05 Sep 2020 01:02:24
User entered 'None (1)'	System	05 Sep 2020 01:02:24

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:19', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e6b0ebf8-1561-4a5d-97f6-a18231508834' User entered '04 Sep 2020 20:02'	System	05 Sep 2020 01:02:24
	System	05 Sep 2020 01:02:24

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 14:51'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 17:21'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:02:37', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '16f459db-0915-4df8-aa4b-8946f8f62df4' User entered 'None (0)'	System	30 Aug 2020 01:03:43
	System	30 Aug 2020 01:03:43

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:02:41', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '16f459db-0915-4df8-aa4b-8946f8f62df4' User entered 'None (0)'	System	30 Aug 2020 01:03:43
	System	30 Aug 2020 01:03:43

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:02:46', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '16f459db-0915-4df8-aa4b-8946f8f62df4' User entered 'None (0)'	System	30 Aug 2020 01:03:43
	System	30 Aug 2020 01:03:43

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:03:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '16f459db-0915-4df8-aa4b-8946f8f62df4' User entered 'None (0)'	System	30 Aug 2020 01:03:43
	System	30 Aug 2020 01:03:43

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:03:07', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '16f459db-0915-4df8-aa4b-8946f8f62df4' User entered 'None (0)'	System	30 Aug 2020 01:03:43
	System	30 Aug 2020 01:03:43

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:03:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '16f459db-0915-4df8-aa4b-8946f8f62df4' User entered 'None (0)'	System	30 Aug 2020 01:03:43
	System	30 Aug 2020 01:03:43

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:03:22', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '16f459db-0915-4df8-aa4b-8946f8f62df4' User entered 'No (N)'	System	30 Aug 2020 01:03:43
	System	30 Aug 2020 01:03:43

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-29T20:03:42', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '16f459db-0915-4df8-aa4b-8946f8f62df4' User entered '29 Aug 2020 20:03'	System	30 Aug 2020 01:03:43
	System	30 Aug 2020 01:03:43

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '29 Aug 2020 18:16'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 2'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:02:54', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '353a1132-57bf-436e-9594-d7970c3b9ff4' User entered 'None (0)'	System	31 Aug 2020 01:03:23
	System	31 Aug 2020 01:03:23

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:02:58', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '353a1132-57bf-436e-9594-d7970c3b9ff4' User entered 'None (0)'	System	31 Aug 2020 01:03:23
	System	31 Aug 2020 01:03:23

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:03:05', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '353a1132-57bf-436e-9594-d7970c3b9ff4' User entered 'None (0)'	System	31 Aug 2020 01:03:23
	System	31 Aug 2020 01:03:23

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:03:08', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '353a1132-57bf-436e-9594-d7970c3b9ff4' User entered 'None (0)'	System	31 Aug 2020 01:03:23
	System	31 Aug 2020 01:03:23

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:03:10', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '353a1132-57bf-436e-9594-d7970c3b9ff4' User entered 'None (0)'	System	31 Aug 2020 01:03:23
	System	31 Aug 2020 01:03:23

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:03:11', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '353a1132-57bf-436e-9594-d7970c3b9ff4' User entered 'None (0)'	System	31 Aug 2020 01:03:23
	System	31 Aug 2020 01:03:23

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:03:17', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '353a1132-57bf-436e-9594-d7970c3b9ff4' User entered 'No (N)'	System	31 Aug 2020 01:03:23
	System	31 Aug 2020 01:03:23

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-30T20:03:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '353a1132-57bf-436e-9594-d7970c3b9ff4' User entered '30 Aug 2020 20:03'	System	31 Aug 2020 01:03:23
	System	31 Aug 2020 01:03:23

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 3'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:01:21', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5a79d24f-94a5-4617-a7ce-82efcef69246' User entered 'None (0)'	System	01 Sep 2020 01:02:55
	System	01 Sep 2020 01:02:55

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:01:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5a79d24f-94a5-4617-a7ce-82efcef69246'	System	01 Sep 2020 01:02:55
User entered 'No interference with activity (1)'	System	01 Sep 2020 01:02:55

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:01:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5a79d24f-94a5-4617-a7ce-82efcef69246' User entered 'None (0)'	System	01 Sep 2020 01:02:55
	System	01 Sep 2020 01:02:55

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:01:37', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5a79d24f-94a5-4617-a7ce-82efcef69246' User entered 'None (0)'	System	01 Sep 2020 01:02:55
	System	01 Sep 2020 01:02:55

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:02:41', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5a79d24f-94a5-4617-a7ce-82efcef69246' User entered 'None (0)'	System	01 Sep 2020 01:02:55
	System	01 Sep 2020 01:02:55

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:02:47', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5a79d24f-94a5-4617-a7ce-82efcef69246' User entered 'None (0)'	System	01 Sep 2020 01:02:55
	System	01 Sep 2020 01:02:55

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:02:50', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5a79d24f-94a5-4617-a7ce-82efcef69246' User entered 'No (N)'	System	01 Sep 2020 01:02:55
	System	01 Sep 2020 01:02:55

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-08-31T20:02:52', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5a79d24f-94a5-4617-a7ce-82efcef69246' User entered '31 Aug 2020 20:02'	System	01 Sep 2020 01:02:55
	System	01 Sep 2020 01:02:55

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 4'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:17', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '77fcb46d-3cf8-46bb-aa9e-8fbf155bc4a4' User entered 'None (0)'	System	02 Sep 2020 01:01:38
	System	02 Sep 2020 01:01:38

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '77fcb46d-3cf8-46bb-aa9e-8fbf155bc4a4'	System	02 Sep 2020 01:01:38
User entered 'None (0)'	System	02 Sep 2020 01:01:38

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '77fcb46d-3cf8-46bb-aa9e-8fbf155bc4a4' User entered 'None (0)'	System	02 Sep 2020 01:01:38
	System	02 Sep 2020 01:01:38

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '77fcb46d-3cf8-46bb-aa9e-8fbf155bc4a4' User entered 'None (0)'	System	02 Sep 2020 01:01:38
	System	02 Sep 2020 01:01:38

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '77fcb46d-3cf8-46bb-aa9e-8fbf155bc4a4'	System	02 Sep 2020 01:01:38
User entered 'None (0)'	System	02 Sep 2020 01:01:38

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:28', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '77fcb46d-3cf8-46bb-aa9e-8fbf155bc4a4' User entered 'None (0)'	System	02 Sep 2020 01:01:38
	System	02 Sep 2020 01:01:38

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:31', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '77fcb46d-3cf8-46bb-aa9e-8fbf155bc4a4'	System	02 Sep 2020 01:01:38
User entered 'No (N)'	System	02 Sep 2020 01:01:38

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-01T20:01:33', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '77fcb46d-3cf8-46bb-aa9e-8fbf155bc4a4'	System	02 Sep 2020 01:01:38
User entered '01 Sep 2020 20:01'	System	02 Sep 2020 01:01:38

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 5'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:02', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '654acc52-ec96-4e4c-8dfd-fe95a254ff43' User entered 'None (0)'	System	03 Sep 2020 01:06:26
	System	03 Sep 2020 01:06:26

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:05', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '654acc52-ec96-4e4c-8dfd-fe95a254ff43' User entered 'None (0)'	System	03 Sep 2020 01:06:26
	System	03 Sep 2020 01:06:26

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:08', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '654acc52-ec96-4e4c-8dfd-fe95a254ff43' User entered 'None (0)'	System	03 Sep 2020 01:06:26
	System	03 Sep 2020 01:06:26

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:09', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '654acc52-ec96-4e4c-8dfd-fe95a254ff43' User entered 'None (0)'	System	03 Sep 2020 01:06:26
	System	03 Sep 2020 01:06:26

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:11', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '654acc52-ec96-4e4c-8dfd-fe95a254ff43' User entered 'None (0)'	System	03 Sep 2020 01:06:26
	System	03 Sep 2020 01:06:26

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:12', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '654acc52-ec96-4e4c-8dfd-fe95a254ff43' User entered 'None (0)'	System	03 Sep 2020 01:06:26
	System	03 Sep 2020 01:06:26

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '654acc52-ec96-4e4c-8dfd-fe95a254ff43'	System	03 Sep 2020 01:06:26
User entered 'No (N)'	System	03 Sep 2020 01:06:26

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-02T20:06:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '654acc52-ec96-4e4c-8dfd-fe95a254ff43'	System	03 Sep 2020 01:06:26
User entered '02 Sep 2020 20:06'	System	03 Sep 2020 01:06:26

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 6'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:45', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '38e06fdc-8aa9-46e5-b417-56972b60af3c' User entered 'None (0)'	System	04 Sep 2020 01:21:15
	System	04 Sep 2020 01:21:15

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:47', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '38e06fdc-8aa9-46e5-b417-56972b60af3c' User entered 'None (0)'	System	04 Sep 2020 01:21:15
	System	04 Sep 2020 01:21:15

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:48', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '38e06fdc-8aa9-46e5-b417-56972b60af3c' User entered 'None (0)'	System	04 Sep 2020 01:21:15
	System	04 Sep 2020 01:21:15

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:50', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '38e06fdc-8aa9-46e5-b417-56972b60af3c' User entered 'None (0)'	System	04 Sep 2020 01:21:15
	System	04 Sep 2020 01:21:15

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '38e06fdc-8aa9-46e5-b417-56972b60af3c' User entered 'None (0)'	System	04 Sep 2020 01:21:15
	System	04 Sep 2020 01:21:15

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:53', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '38e06fdc-8aa9-46e5-b417-56972b60af3c' User entered 'None (0)'	System	04 Sep 2020 01:21:15
	System	04 Sep 2020 01:21:15

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:20:54', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '38e06fdc-8aa9-46e5-b417-56972b60af3c' User entered 'No (N)'	System	04 Sep 2020 01:21:15
	System	04 Sep 2020 01:21:15

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90C3194-2072-45A0-941C-431F71F5D091)', Time: '2020-09-03T20:21:09', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '38e06fdc-8aa9-46e5-b417-56972b60af3c' User entered '03 Sep 2020 20:21'	System	04 Sep 2020 01:21:15
	System	04 Sep 2020 01:21:15

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 7'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'abccc16e-a029-4c28-98e6-7249902175fa' User entered 'None (0)'	System	05 Sep 2020 01:02:54
	System	05 Sep 2020 01:02:54

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'abccc16e-a029-4c28-98e6-7249902175fa' User entered 'None (0)'	System	05 Sep 2020 01:02:54
	System	05 Sep 2020 01:02:54

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:27', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'abccc16e-a029-4c28-98e6-7249902175fa' User entered 'None (0)'	System	05 Sep 2020 01:02:54
	System	05 Sep 2020 01:02:54

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:29', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'abccc16e-a029-4c28-98e6-7249902175fa' User entered 'None (0)'	System	05 Sep 2020 01:02:54
	System	05 Sep 2020 01:02:54

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:31', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'abccc16e-a029-4c28-98e6-7249902175fa' User entered 'None (0)'	System	05 Sep 2020 01:02:54
	System	05 Sep 2020 01:02:54

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:34', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'abccc16e-a029-4c28-98e6-7249902175fa' User entered 'None (0)'	System	05 Sep 2020 01:02:54
	System	05 Sep 2020 01:02:54

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:46', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'abccc16e-a029-4c28-98e6-7249902175fa' User entered 'No (N)'	System	05 Sep 2020 01:02:54
	System	05 Sep 2020 01:02:54

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-09-04T20:02:48', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'abccc16e-a029-4c28-98e6-7249902175fa' User entered '04 Sep 2020 20:02'	System	05 Sep 2020 01:02:54
	System	05 Sep 2020 01:02:54

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 19:34:53

US3552240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Joan Siegner (b) (4)	05 Sep 2020 17:01:56

US3552240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '05 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 19:16:40
User entered '5 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	05 Sep 2020 17:01:56

US3552240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4) [REDACTED]	05 Sep 2020 17:01:56

US3552240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 17:01:56

US3552240

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 16:35:58

US3552240

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'l'	System	12 Sep 2020 16:35:58

US3552240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 16:36:09

US3552240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '12 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 16:36:09

US3552240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 16:36:09

US3552240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 16:36:09

US3552240

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	19 Sep 2020 19:05:03

US3552240

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'l'	System	19 Sep 2020 19:05:03

US3552240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Joan Siegner (b) (4)	19 Sep 2020 19:05:13

US3552240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '19 Sep 2020'	(b) (4) Joan Siegner (b) (4)	19 Sep 2020 19:05:13

US3552240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4) [REDACTED]	19 Sep 2020 19:05:13

US3552240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Joan Siegner (b) (4)	19 Sep 2020 19:05:13

US3552240

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:18:24

US3552240

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'l'	System	01 Oct 2020 17:18:24

US3552240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:19

US3552240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '01 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 19:16:56
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:19

US3552240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:19

US3552240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'VISIT2'	System	01 Oct 2020 19:25:19

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '01 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 19:17:04
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '11:40'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '01 Oct 2020 11:40'	System	10 Nov 2020 19:17:04
User entered '1 Oct 2020 11:40'	System	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '97.7' F	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '70'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'bpm'	System	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '16'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'breaths/min'	System	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '138'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'mmHg'	System	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '86'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'mmHg'	System	01 Oct 2020 19:25:45

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '01 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 19:17:04
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '13:06'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '01 Oct 2020 13:06'	System	10 Nov 2020 19:17:04
User entered '1 Oct 2020 13:06'	System	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '98' F	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '82'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'bpm'	System	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '16'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'breaths/min'	System	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '134'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'mmHg'	System	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '82'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'mmHg'	System	01 Oct 2020 19:26:17

US3552240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:27:55

US3552240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	10 Nov 2020 19:17:10
User entered '1 Oct 2020'	(b) (4)	
	Stanley Dublin (b) (4)	01 Oct 2020 19:27:55
	(b) (4)	

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '01 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 19:17:18
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '12:36'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '01 Oct 2020 12:36'	System	10 Nov 2020 19:17:18
User entered '1 Oct 2020 12:36'	System	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'ONCE'	System	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 18:03:51

US3552240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:06

US3552240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '01 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 19:17:24
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:06

US3552240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '12:08'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:06

US3552240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '01 Oct 2020 12:08'	System	10 Nov 2020 19:17:24
User entered '1 Oct 2020 12:08'	System	01 Oct 2020 19:28:06

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '01 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 19:17:31
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '12:11'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '01 Oct 2020 12:11'	System	10 Nov 2020 19:17:31
User entered '1 Oct 2020 12:11'	System	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered empty.	System	01 Oct 2020 19:28:21

US3552240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 17:55:04

US3552240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'I'	System	08 Oct 2020 17:55:04

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:04:19', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '3255a954-b573-4494-a2e1-de1c2f16e349' User entered 'Yes (Y)'	System	01 Oct 2020 18:04:31
	System	01 Oct 2020 18:04:31

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:04:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '3255a954-b573-4494-a2e1-de1c2f16e349' User entered '98.0'	System	01 Oct 2020 18:04:31
	System	01 Oct 2020 18:04:31

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:04:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '3255a954-b573-4494-a2e1-de1c2f16e349'	System	01 Oct 2020 18:04:31
User entered 'No (N)'	System	01 Oct 2020 18:04:31

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:04:29', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '3255a954-b573-4494-a2e1-de1c2f16e349' User entered '01 Oct 2020 13:04'	System	01 Oct 2020 18:04:31
	System	01 Oct 2020 18:04:31

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 12:56'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 15:26'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:18:31', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '385b95b3-a469-48ca-9f1e-4e00eedc0622' User entered 'Yes (Y)'	System	02 Oct 2020 01:18:44
	System	02 Oct 2020 01:18:44

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:18:35', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '385b95b3-a469-48ca-9f1e-4e00eedc0622' User entered '98.4'	System	02 Oct 2020 01:18:44
	System	02 Oct 2020 01:18:44

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:18:38', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '385b95b3-a469-48ca-9f1e-4e00eedc0622' User entered 'No (N)'	System	02 Oct 2020 01:18:44
	System	02 Oct 2020 01:18:44

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:18:41', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '385b95b3-a469-48ca-9f1e-4e00eedc0622' User entered '01 Oct 2020 20:18'	System	02 Oct 2020 01:18:44
	System	02 Oct 2020 01:18:44

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 16:21'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 2'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:49:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b36b43ab-43ea-4c8c-b860-3b56617a5694' User entered 'Yes (Y)'	System	03 Oct 2020 09:49:35
	System	03 Oct 2020 09:49:35

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:49:19', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b36b43ab-43ea-4c8c-b860-3b56617a5694' User entered '97.5'	System	03 Oct 2020 09:49:35
	System	03 Oct 2020 09:49:35

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:49:27', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b36b43ab-43ea-4c8c-b860-3b56617a5694'	System	03 Oct 2020 09:49:35
User entered 'No (N)'	System	03 Oct 2020 09:49:35

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:49:31', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b36b43ab-43ea-4c8c-b860-3b56617a5694' User entered '03 Oct 2020 04:49'	System	03 Oct 2020 09:49:35
	System	03 Oct 2020 09:49:35

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 3'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9f7c48e9-eacc-41b9-850e-2943fc207a28'	System	04 Oct 2020 02:32:32
User entered 'Yes (Y)'	System	04 Oct 2020 02:32:32

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9f7c48e9-eacc-41b9-850e-2943fc207a28' User entered '97.5'	System	04 Oct 2020 02:32:32
	System	04 Oct 2020 02:32:32

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9f7c48e9-eacc-41b9-850e-2943fc207a28'	System	04 Oct 2020 02:32:32
User entered 'No (N)'	System	04 Oct 2020 02:32:32

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:27', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9f7c48e9-eacc-41b9-850e-2943fc207a28' User entered '03 Oct 2020 21:32'	System	04 Oct 2020 02:32:32
	System	04 Oct 2020 02:32:32

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 4'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:04', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5ca3f8d5-086a-4edf-86dc-a17b5a544f13' User entered 'Yes (Y)'	System	05 Oct 2020 09:10:19
	System	05 Oct 2020 09:10:19

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:10', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5ca3f8d5-086a-4edf-86dc-a17b5a544f13' User entered '97.2'	System	05 Oct 2020 09:10:19
	System	05 Oct 2020 09:10:19

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:14', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5ca3f8d5-086a-4edf-86dc-a17b5a544f13'	System	05 Oct 2020 09:10:19
User entered 'No (N)'	System	05 Oct 2020 09:10:19

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:16', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5ca3f8d5-086a-4edf-86dc-a17b5a544f13' User entered '05 Oct 2020 04:10'	System	05 Oct 2020 09:10:19
	System	05 Oct 2020 09:10:19

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 5'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:28', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '983553fc-4c57-473c-b9b2-14e2416f7c1f' User entered 'Yes (Y)'	System	06 Oct 2020 00:20:40
	System	06 Oct 2020 00:20:40

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:32', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '983553fc-4c57-473c-b9b2-14e2416f7c1f' User entered '97.8'	System	06 Oct 2020 00:20:40
	System	06 Oct 2020 00:20:40

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:34', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '983553fc-4c57-473c-b9b2-14e2416f7c1f' User entered 'No (N)'	System	06 Oct 2020 00:20:40
	System	06 Oct 2020 00:20:40

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:38', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '983553fc-4c57-473c-b9b2-14e2416f7c1f' User entered '05 Oct 2020 19:20'	System	06 Oct 2020 00:20:40
	System	06 Oct 2020 00:20:40

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 6'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:02', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6d348d39-bf93-419c-a7ef-38c296161f79' User entered 'Yes (Y)'	System	07 Oct 2020 14:35:15
	System	07 Oct 2020 14:35:15

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:07', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6d348d39-bf93-419c-a7ef-38c296161f79' User entered '97.4'	System	07 Oct 2020 14:35:15
	System	07 Oct 2020 14:35:15

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:10', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6d348d39-bf93-419c-a7ef-38c296161f79'	System	07 Oct 2020 14:35:15
User entered 'No (N)'	System	07 Oct 2020 14:35:15

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6d348d39-bf93-419c-a7ef-38c296161f79' User entered '07 Oct 2020 09:35'	System	07 Oct 2020 14:35:15
	System	07 Oct 2020 14:35:15

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 7'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:50:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ece220d8-a014-43c7-b93c-8721fb98b1d2' User entered 'Yes (Y)'	System	07 Oct 2020 19:51:02
	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:50:31', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ece220d8-a014-43c7-b93c-8721fb98b1d2' User entered '97.6'	System	07 Oct 2020 19:51:02
	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:50:44', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ece220d8-a014-43c7-b93c-8721fb98b1d2'	System	07 Oct 2020 19:51:02
User entered 'Yes (Y)'	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted and data updated accordingly' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 08:41:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:50:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ece220d8-a014-43c7-b93c-8721fb98b1d2' User entered '1'	Cassandra Zehenny (b) (4)	09 Oct 2020 14:13:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Oct 2020 19:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:50:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ece220d8-a014-43c7-b93c-8721fb98b1d2' User entered '1'	System	07 Oct 2020 19:51:02
User entered '1'	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:50:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ece220d8-a014-43c7-b93c-8721fb98b1d2' User entered '0'	System	07 Oct 2020 19:51:02
	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:50:59', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ece220d8-a014-43c7-b93c-8721fb98b1d2' User entered '07 Oct 2020 14:50'	System	07 Oct 2020 19:51:02
	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	07 Oct 2020 19:51:02
User entered 'Day 8'	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:12:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-08T20:19:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '869b720f-8dd1-4d41-ac2d-61b20b4ecb7f' User entered 'Yes (Y)'	System	09 Oct 2020 01:19:26
	System	09 Oct 2020 01:19:26

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:12:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-08T20:19:17', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '869b720f-8dd1-4d41-ac2d-61b20b4ecb7f' User entered '97.6'	System	09 Oct 2020 01:19:26
	System	09 Oct 2020 01:19:26

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-08T20:19:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '869b720f-8dd1-4d41-ac2d-61b20b4ecb7f' User entered 'No (N)'	System	09 Oct 2020 01:19:26
	System	09 Oct 2020 01:19:26

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-08T20:19:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '869b720f-8dd1-4d41-ac2d-61b20b4ecb7f' User entered '08 Oct 2020 20:19'	System	09 Oct 2020 01:19:26
	System	09 Oct 2020 01:19:26

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:18', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '03f8919b-9db7-4413-8154-6be94a1402fa' User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 18:05:38
	System	01 Oct 2020 18:05:38

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:21', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '03f8919b-9db7-4413-8154-6be94a1402fa' User entered 'No (N)'	System	01 Oct 2020 18:05:38
	System	01 Oct 2020 18:05:38

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '03f8919b-9db7-4413-8154-6be94a1402fa' User entered 'No (N)'	System	01 Oct 2020 18:05:38
	System	01 Oct 2020 18:05:38

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:31', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '03f8919b-9db7-4413-8154-6be94a1402fa'	System	01 Oct 2020 18:05:38
User entered 'None (1)'	System	01 Oct 2020 18:05:38

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:33', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '03f8919b-9db7-4413-8154-6be94a1402fa' User entered '01 Oct 2020 13:05'	System	01 Oct 2020 18:05:38
	System	01 Oct 2020 18:05:38

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 12:56'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 15:26'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:14:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '204de64a-fe2c-4621-9e77-edeb1a06f87'	System	02 Oct 2020 01:14:49
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 01:14:49

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:14:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '204de64a-fe2c-4621-9e77-edeb1a06f87'	System	02 Oct 2020 01:14:49
User entered 'No (N)'	System	02 Oct 2020 01:14:49

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:14:27', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '204de64a-fe2c-4621-9e77-edeb1a06f87'	System	02 Oct 2020 01:14:49
User entered 'No (N)'	System	02 Oct 2020 01:14:49

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:14:41', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '204de64a-fe2c-4621-9e77-edeb1a06f87'	System	02 Oct 2020 01:14:49
User entered 'None (1)'	System	02 Oct 2020 01:14:49

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:14:45', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '204de64a-fe2c-4621-9e77-edeb1a06f87' User entered '01 Oct 2020 20:14'	System	02 Oct 2020 01:14:49
	System	02 Oct 2020 01:14:49

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 16:21'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 2'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:49:43', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '22a0960a-5b18-436a-a266-526a0b1b4509'	System	03 Oct 2020 09:50:12
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 09:50:12

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:49:56', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '22a0960a-5b18-436a-a266-526a0b1b4509' User entered 'No (N)'	System	03 Oct 2020 09:50:12
	System	03 Oct 2020 09:50:12

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:49:58', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '22a0960a-5b18-436a-a266-526a0b1b4509' User entered 'No (N)'	System	03 Oct 2020 09:50:12
	System	03 Oct 2020 09:50:12

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:50:03', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '22a0960a-5b18-436a-a266-526a0b1b4509'	System	03 Oct 2020 09:50:12
User entered 'None (1)'	System	03 Oct 2020 09:50:12

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:50:08', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '22a0960a-5b18-436a-a266-526a0b1b4509' User entered '03 Oct 2020 04:50'	System	03 Oct 2020 09:50:12
	System	03 Oct 2020 09:50:12

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 3'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:35', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '434199a7-baa5-4db5-8f53-228108a7beee'	System	04 Oct 2020 02:32:53
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 02:32:53

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:38', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '434199a7-baa5-4db5-8f53-228108a7beec' User entered 'No (N)'	System	04 Oct 2020 02:32:53
	System	04 Oct 2020 02:32:53

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:43', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '434199a7-baa5-4db5-8f53-228108a7beee' User entered 'No (N)'	System	04 Oct 2020 02:32:53
	System	04 Oct 2020 02:32:53

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:48', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '434199a7-baa5-4db5-8f53-228108a7beee' User entered 'None (1)'	System	04 Oct 2020 02:32:53
	System	04 Oct 2020 02:32:53

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '434199a7-baa5-4db5-8f53-228108a7beee' User entered '03 Oct 2020 21:32'	System	04 Oct 2020 02:32:53
	System	04 Oct 2020 02:32:53

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 4'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c13baa65-455f-44d7-8850-91de2d2f3450'	System	05 Oct 2020 09:10:37
User entered 'None (1)'	System	05 Oct 2020 09:10:37

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c13baa65-455f-44d7-8850-91de2d2f3450'	System	05 Oct 2020 09:10:37
User entered 'No (N)'	System	05 Oct 2020 09:10:37

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c13baa65-455f-44d7-8850-91de2d2f3450' User entered 'No (N)'	System	05 Oct 2020 09:10:37
	System	05 Oct 2020 09:10:37

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:29', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c13baa65-455f-44d7-8850-91de2d2f3450'	System	05 Oct 2020 09:10:37
User entered 'None (1)'	System	05 Oct 2020 09:10:37

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:32', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'c13baa65-455f-44d7-8850-91de2d2f3450' User entered '05 Oct 2020 04:10'	System	05 Oct 2020 09:10:37
	System	05 Oct 2020 09:10:37

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 5'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:44', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '2d67fe88-6063-44ce-b631-cc0c4a9b3e64'	System	06 Oct 2020 00:20:54
User entered 'Does not interfere with activity (2)'	System	06 Oct 2020 00:20:54

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:46', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '2d67fe88-6063-44ce-b631-cc0c4a9b3e64'	System	06 Oct 2020 00:20:54
User entered 'No (N)'	System	06 Oct 2020 00:20:54

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:48', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '2d67fe88-6063-44ce-b631-cc0c4a9b3e64' User entered 'No (N)'	System	06 Oct 2020 00:20:54
	System	06 Oct 2020 00:20:54

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:50', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '2d67fe88-6063-44ce-b631-cc0c4a9b3e64'	System	06 Oct 2020 00:20:54
User entered 'None (1)'	System	06 Oct 2020 00:20:54

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:53', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '2d67fe88-6063-44ce-b631-cc0c4a9b3e64' User entered '05 Oct 2020 19:20'	System	06 Oct 2020 00:20:54
	System	06 Oct 2020 00:20:54

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 6'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:17', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b7dc7b0-ae30-42b3-961d-adce9b105b7a' User entered 'None (1)'	System	07 Oct 2020 14:35:31
	System	07 Oct 2020 14:35:31

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:22', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b7dc7b0-ae30-42b3-961d-adce9b105b7a' User entered 'No (N)'	System	07 Oct 2020 14:35:31
	System	07 Oct 2020 14:35:31

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:24', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b7dc7b0-ae30-42b3-961d-adce9b105b7a' User entered 'No (N)'	System	07 Oct 2020 14:35:31
	System	07 Oct 2020 14:35:31

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b7dc7b0-ae30-42b3-961d-adce9b105b7a' User entered 'None (1)'	System	07 Oct 2020 14:35:31
	System	07 Oct 2020 14:35:31

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:28', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5b7dc7b0-ae30-42b3-961d-adce9b105b7a' User entered '07 Oct 2020 09:35'	System	07 Oct 2020 14:35:31
	System	07 Oct 2020 14:35:31

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 7'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:51:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '80fd7efa-2a33-4019-b255-6092e1c98e1a' User entered 'None (1)'	System	07 Oct 2020 19:51:56
	System	07 Oct 2020 19:51:56

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:51:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '80fd7efa-2a33-4019-b255-6092e1c98e1a' User entered 'No (N)'	System	07 Oct 2020 19:51:56
	System	07 Oct 2020 19:51:56

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:51:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '80fd7efa-2a33-4019-b255-6092e1c98e1a' User entered 'No (N)'	System	07 Oct 2020 19:51:56
	System	07 Oct 2020 19:51:56

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:51:48', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '80fd7efa-2a33-4019-b255-6092e1c98e1a' User entered 'None (1)'	System	07 Oct 2020 19:51:56
	System	07 Oct 2020 19:51:56

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:51:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '80fd7efa-2a33-4019-b255-6092e1c98e1a' User entered '07 Oct 2020 14:51'	System	07 Oct 2020 19:51:56
	System	07 Oct 2020 19:51:56

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:38', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed7c3109-efe2-4760-8ca5-0c6651d18098' User entered 'None (0)'	System	01 Oct 2020 18:06:03
	System	01 Oct 2020 18:06:03

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:44', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed7c3109-efe2-4760-8ca5-0c6651d18098' User entered 'None (0)'	System	01 Oct 2020 18:06:03
	System	01 Oct 2020 18:06:03

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:47', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed7c3109-efe2-4760-8ca5-0c6651d18098' User entered 'None (0)'	System	01 Oct 2020 18:06:03
	System	01 Oct 2020 18:06:03

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed7c3109-efe2-4760-8ca5-0c6651d18098' User entered 'None (0)'	System	01 Oct 2020 18:06:03
	System	01 Oct 2020 18:06:03

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:53', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed7c3109-efe2-4760-8ca5-0c6651d18098' User entered 'None (0)'	System	01 Oct 2020 18:06:03
	System	01 Oct 2020 18:06:03

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:54', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed7c3109-efe2-4760-8ca5-0c6651d18098' User entered 'None (0)'	System	01 Oct 2020 18:06:03
	System	01 Oct 2020 18:06:03

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:57', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed7c3109-efe2-4760-8ca5-0c6651d18098' User entered 'No (N)'	System	01 Oct 2020 18:06:03
	System	01 Oct 2020 18:06:03

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T13:05:59', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed7c3109-efe2-4760-8ca5-0c6651d18098' User entered '01 Oct 2020 13:05'	System	01 Oct 2020 18:06:03
	System	01 Oct 2020 18:06:03

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 12:56'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 15:26'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:14:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9b65f8ab-121e-4c99-9437-d1459d131bd1' User entered 'None (0)'	System	02 Oct 2020 01:15:23
	System	02 Oct 2020 01:15:23

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:14:54', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9b65f8ab-121e-4c99-9437-d1459d131bd1' User entered 'None (0)'	System	02 Oct 2020 01:15:23
	System	02 Oct 2020 01:15:23

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:14:58', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9b65f8ab-121e-4c99-9437-d1459d131bd1' User entered 'None (0)'	System	02 Oct 2020 01:15:23
	System	02 Oct 2020 01:15:23

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:15:03', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9b65f8ab-121e-4c99-9437-d1459d131bd1' User entered 'None (0)'	System	02 Oct 2020 01:15:23
	System	02 Oct 2020 01:15:23

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:15:06', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9b65f8ab-121e-4c99-9437-d1459d131bd1' User entered 'None (0)'	System	02 Oct 2020 01:15:23
	System	02 Oct 2020 01:15:23

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:15:08', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9b65f8ab-121e-4c99-9437-d1459d131bd1' User entered 'None (0)'	System	02 Oct 2020 01:15:23
	System	02 Oct 2020 01:15:23

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:15:14', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9b65f8ab-121e-4c99-9437-d1459d131bd1' User entered 'No (N)'	System	02 Oct 2020 01:15:23
	System	02 Oct 2020 01:15:23

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-01T20:15:18', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9b65f8ab-121e-4c99-9437-d1459d131bd1' User entered '01 Oct 2020 20:15'	System	02 Oct 2020 01:15:23
	System	02 Oct 2020 01:15:23

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '01 Oct 2020 16:21'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 2'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:50:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '940513d7-2136-4d62-b60e-36601a30fe31' User entered 'None (0)'	System	03 Oct 2020 09:51:17
	System	03 Oct 2020 09:51:17

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:50:17', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '940513d7-2136-4d62-b60e-36601a30fe31' User entered 'None (0)'	System	03 Oct 2020 09:51:17
	System	03 Oct 2020 09:51:17

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:50:39', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '940513d7-2136-4d62-b60e-36601a30fe31' User entered 'None (0)'	System	03 Oct 2020 09:51:17
	System	03 Oct 2020 09:51:17

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:50:41', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '940513d7-2136-4d62-b60e-36601a30fe31' User entered 'No interference with activity (1)'	System	03 Oct 2020 09:51:17
	System	03 Oct 2020 09:51:17

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:50:44', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '940513d7-2136-4d62-b60e-36601a30fe31' User entered 'None (0)'	System	03 Oct 2020 09:51:17
	System	03 Oct 2020 09:51:17

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:51:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '940513d7-2136-4d62-b60e-36601a30fe31' User entered 'None (0)'	System	03 Oct 2020 09:51:17
	System	03 Oct 2020 09:51:17

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:51:10', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '940513d7-2136-4d62-b60e-36601a30fe31' User entered 'No (N)'	System	03 Oct 2020 09:51:17
	System	03 Oct 2020 09:51:17

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T04:51:14', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '940513d7-2136-4d62-b60e-36601a30fe31' User entered '03 Oct 2020 04:51'	System	03 Oct 2020 09:51:17
	System	03 Oct 2020 09:51:17

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 3'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:32:58', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5d7369dc-8622-474b-9507-0a63b6591546' User entered 'None (0)'	System	04 Oct 2020 02:33:29
	System	04 Oct 2020 02:33:29

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:33:01', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5d7369dc-8622-474b-9507-0a63b6591546' User entered 'None (0)'	System	04 Oct 2020 02:33:29
	System	04 Oct 2020 02:33:29

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:33:05', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5d7369dc-8622-474b-9507-0a63b6591546' User entered 'None (0)'	System	04 Oct 2020 02:33:29
	System	04 Oct 2020 02:33:29

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:33:11', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5d7369dc-8622-474b-9507-0a63b6591546' User entered 'None (0)'	System	04 Oct 2020 02:33:29
	System	04 Oct 2020 02:33:29

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:33:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5d7369dc-8622-474b-9507-0a63b6591546' User entered 'None (0)'	System	04 Oct 2020 02:33:29
	System	04 Oct 2020 02:33:29

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:33:21', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5d7369dc-8622-474b-9507-0a63b6591546' User entered 'None (0)'	System	04 Oct 2020 02:33:29
	System	04 Oct 2020 02:33:29

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:33:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5d7369dc-8622-474b-9507-0a63b6591546' User entered 'No (N)'	System	04 Oct 2020 02:33:29
	System	04 Oct 2020 02:33:29

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-03T21:33:28', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '5d7369dc-8622-474b-9507-0a63b6591546' User entered '03 Oct 2020 21:33'	System	04 Oct 2020 02:33:29
	System	04 Oct 2020 02:33:29

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 4'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:36', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b3eabdfa-f562-4662-9592-c3e530a047e7' User entered 'None (0)'	System	05 Oct 2020 09:10:55
	System	05 Oct 2020 09:10:55

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:38', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b3eabdfa-f562-4662-9592-c3e530a047e7' User entered 'None (0)'	System	05 Oct 2020 09:10:55
	System	05 Oct 2020 09:10:55

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:40', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b3eabdfa-f562-4662-9592-c3e530a047e7' User entered 'None (0)'	System	05 Oct 2020 09:10:55
	System	05 Oct 2020 09:10:55

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:42', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b3eabdfa-f562-4662-9592-c3e530a047e7' User entered 'None (0)'	System	05 Oct 2020 09:10:55
	System	05 Oct 2020 09:10:55

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:44', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b3eabdfa-f562-4662-9592-c3e530a047e7' User entered 'None (0)'	System	05 Oct 2020 09:10:55
	System	05 Oct 2020 09:10:55

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:46', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b3eabdfa-f562-4662-9592-c3e530a047e7' User entered 'None (0)'	System	05 Oct 2020 09:10:55
	System	05 Oct 2020 09:10:55

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:48', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b3eabdfa-f562-4662-9592-c3e530a047e7' User entered 'No (N)'	System	05 Oct 2020 09:10:55
	System	05 Oct 2020 09:10:55

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T04:10:53', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b3eabdfa-f562-4662-9592-c3e530a047e7' User entered '05 Oct 2020 04:10'	System	05 Oct 2020 09:10:55
	System	05 Oct 2020 09:10:55

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 5'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:56', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '260a5f84-19e7-453c-be50-aafd04af53cc' User entered 'None (0)'	System	06 Oct 2020 00:21:14
	System	06 Oct 2020 00:21:14

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:20:59', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '260a5f84-19e7-453c-be50-aafd04af53cc' User entered 'None (0)'	System	06 Oct 2020 00:21:14
	System	06 Oct 2020 00:21:14

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:21:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '260a5f84-19e7-453c-be50-aafd04af53cc' User entered 'None (0)'	System	06 Oct 2020 00:21:14
	System	06 Oct 2020 00:21:14

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:21:03', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '260a5f84-19e7-453c-be50-aafd04af53cc' User entered 'None (0)'	System	06 Oct 2020 00:21:14
	System	06 Oct 2020 00:21:14

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:21:06', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '260a5f84-19e7-453c-be50-aafd04af53cc' User entered 'None (0)'	System	06 Oct 2020 00:21:14
	System	06 Oct 2020 00:21:14

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:21:08', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '260a5f84-19e7-453c-be50-aafd04af53cc' User entered 'None (0)'	System	06 Oct 2020 00:21:14
	System	06 Oct 2020 00:21:14

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:21:10', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '260a5f84-19e7-453c-be50-aafd04af53cc'	System	06 Oct 2020 00:21:14
User entered 'No (N)'	System	06 Oct 2020 00:21:14

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-05T19:21:12', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '260a5f84-19e7-453c-be50-aafd04af53cc' User entered '05 Oct 2020 19:21'	System	06 Oct 2020 00:21:14
	System	06 Oct 2020 00:21:14

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 6'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:35', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e0a87793-2281-4d0e-ae7c-1da5c5cdc889' User entered 'None (0)'	System	07 Oct 2020 14:35:50
	System	07 Oct 2020 14:35:50

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:36', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e0a87793-2281-4d0e-ae7c-1da5c5cdc889' User entered 'None (0)'	System	07 Oct 2020 14:35:50
	System	07 Oct 2020 14:35:50

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:37', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e0a87793-2281-4d0e-ae7c-1da5c5cdc889' User entered 'None (0)'	System	07 Oct 2020 14:35:50
	System	07 Oct 2020 14:35:50

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:38', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e0a87793-2281-4d0e-ae7c-1da5c5cdc889' User entered 'None (0)'	System	07 Oct 2020 14:35:50
	System	07 Oct 2020 14:35:50

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:40', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e0a87793-2281-4d0e-ae7c-1da5c5cdc889' User entered 'None (0)'	System	07 Oct 2020 14:35:50
	System	07 Oct 2020 14:35:50

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:41', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e0a87793-2281-4d0e-ae7c-1da5c5cdc889' User entered 'None (0)'	System	07 Oct 2020 14:35:50
	System	07 Oct 2020 14:35:50

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:43', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e0a87793-2281-4d0e-ae7c-1da5c5cdc889'	System	07 Oct 2020 14:35:50
User entered 'No (N)'	System	07 Oct 2020 14:35:50

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T09:35:45', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e0a87793-2281-4d0e-ae7c-1da5c5cdc889' User entered '07 Oct 2020 09:35'	System	07 Oct 2020 14:35:50
	System	07 Oct 2020 14:35:50

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	01 Oct 2020 18:03:51
User entered 'Day 7'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:52:13', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'df33d222-97f3-41d2-a826-8859dcf3f61e'	System	07 Oct 2020 19:52:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:52:17', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'df33d222-97f3-41d2-a826-8859dcf3f61e' User entered 'None (0)'	System	07 Oct 2020 19:52:34
	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:52:19', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'df33d222-97f3-41d2-a826-8859dcf3f61e' User entered 'None (0)'	System	07 Oct 2020 19:52:34
	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:52:21', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'df33d222-97f3-41d2-a826-8859dcf3f61e' User entered 'None (0)'	System	07 Oct 2020 19:52:34
	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:52:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'df33d222-97f3-41d2-a826-8859dcf3f61e' User entered 'None (0)'	System	07 Oct 2020 19:52:34
	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:52:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'df33d222-97f3-41d2-a826-8859dcf3f61e' User entered 'None (0)'	System	07 Oct 2020 19:52:34
	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:52:28', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'df33d222-97f3-41d2-a826-8859dcf3f61e' User entered 'No (N)'	System	07 Oct 2020 19:52:34
	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-07T14:52:30', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'df33d222-97f3-41d2-a826-8859dcf3f61e' User entered '07 Oct 2020 14:52'	System	07 Oct 2020 19:52:34
	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:03:51

US3552240

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	07 Oct 2020 19:52:34
User entered 'Day 8'	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:12:45

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-08T20:19:30', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9dd568cc-988b-46f1-a0a1-1f87cfed99a6' User entered 'None (0)'	System	09 Oct 2020 01:19:34
	System	09 Oct 2020 01:19:34

US3552240

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-08T20:19:33', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '9dd568cc-988b-46f1-a0a1-1f87cfed99a6' User entered '08 Oct 2020 20:19'	System	09 Oct 2020 01:19:34
	System	09 Oct 2020 01:19:34

US3552240

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 19:52:34

US3552240

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	07 Oct 2020 19:51:02
User entered 'Day 8'	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:12:45

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 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-08T20:19:39', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e337522b-9f94-4f33-9f8e-13d20fec19eb' User entered 'No (N)'	System	09 Oct 2020 01:19:45
	System	09 Oct 2020 01:19:45

US3552240

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-10-08T20:19:42', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e337522b-9f94-4f33-9f8e-13d20fec19eb' User entered '08 Oct 2020 20:19'	System	09 Oct 2020 01:19:45
	System	09 Oct 2020 01:19:45

US3552240

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 19:51:02

US3552240

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:12:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 19:51:02

US3552240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 17:55:16

US3552240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '08 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 19:16:48
User entered '8 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 17:55:16

US3552240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 17:55:16

US3552240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 17:55:16

US3552240

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 17:11:34

US3552240

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'l'	System	15 Oct 2020 17:11:34

US3552240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 17:11:41

US3552240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 17:11:41

US3552240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 17:11:41

US3552240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 17:11:41

US3552240

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:24:35

US3552240

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'l'	System	22 Oct 2020 16:24:35

US3552240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:24:46

US3552240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '22 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:24:46

US3552240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:24:46

US3552240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:24:46

US3552240

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:30

US3552240

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'l'	System	30 Oct 2020 17:42:30

US3552240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:38

US3552240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '30 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:38

US3552240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:38

US3552240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'VISIT3'	System	30 Oct 2020 17:42:38

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered empty.	System	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered empty.	System	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered empty.	System	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered empty.	System	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered empty.	System	30 Oct 2020 17:42:42

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05

US3552240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05

US3552240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:43:01

US3552240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:43:01

US3552240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:43:10

US3552240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '30 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:43:10

US3552240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '11:59'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 17:43:10

US3552240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered '30 Oct 2020 11:59'	System	30 Oct 2020 17:43:10

US3552240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:58:24

US3552240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'I'	System	23 Nov 2020 19:58:24

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 64'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-02T15:02:10', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b08bf005-ed64-4635-b998-857c0d1d8bb6'	System	02 Nov 2020 21:02:21
User entered 'No (N)'	System	02 Nov 2020 21:02:21

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-02T15:02:16', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b08bf005-ed64-4635-b998-857c0d1d8bb6'	System	02 Nov 2020 21:02:21
User entered 'No (N)'	System	02 Nov 2020 21:02:21

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-02T15:02:19', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'b08bf005-ed64-4635-b998-857c0d1d8bb6'	System	02 Nov 2020 21:02:21
User entered '02 Nov 2020 15:02:19'	System	02 Nov 2020 21:02:21

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 71'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-09T07:00:03', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23ec2a87-ed80-4b82-8450-e00ffdba531b' User entered 'No (N)'	System	09 Nov 2020 13:00:14
	System	09 Nov 2020 13:00:14

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-09T07:00:07', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23ec2a87-ed80-4b82-8450-e00ffdba531b' User entered 'No (N)'	System	09 Nov 2020 13:00:14
	System	09 Nov 2020 13:00:14

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-09T07:00:11', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23ec2a87-ed80-4b82-8450-e00ffdba531b' User entered '09 Nov 2020 07:00:11'	System	09 Nov 2020 13:00:14
	System	09 Nov 2020 13:00:14

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered 'Day 78'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-15T19:55:50', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'd69221c8-d563-444f-a1da-e03a1da141e7'	System	16 Nov 2020 01:55:58
User entered 'No (N)'	System	16 Nov 2020 01:55:58

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-15T19:55:53', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'd69221c8-d563-444f-a1da-e03a1da141e7'	System	16 Nov 2020 01:55:58
User entered 'No (N)'	System	16 Nov 2020 01:55:58

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-15T19:55:55', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'd69221c8-d563-444f-a1da-e03a1da141e7' User entered '15 Nov 2020 19:55:55'	System	16 Nov 2020 01:55:58
	System	16 Nov 2020 01:55:58

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 19:34:53

US3552240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:42
Data entry locked.	System	29 Aug 2020 19:34:53
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 19:34:53

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-23T13:09:37', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'dd54ca3a-b44a-4c66-a00d-50ef88fa86a7' User entered 'No (N)'	System	23 Nov 2020 19:09:47

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-23T13:09:40', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'dd54ca3a-b44a-4c66-a00d-50ef88fa86a7' User entered 'No (N)'	System	23 Nov 2020 19:09:47

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-23T13:09:42', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'dd54ca3a-b44a-4c66-a00d-50ef88fa86a7' User entered '23 Nov 2020 13:09:42'	System	23 Nov 2020 19:09:47
	System	23 Nov 2020 19:09:47

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-30T19:55:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'd4ce7f52-5da9-4311-8628-bb317620215f' User entered 'No (N)'	System	01 Dec 2020 01:55:27
	System	01 Dec 2020 01:55:27

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-30T19:55:22', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'd4ce7f52-5da9-4311-8628-bb317620215f' User entered 'No (N)'	System	01 Dec 2020 01:55:27

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-11-30T19:55:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'd4ce7f52-5da9-4311-8628-bb317620215f' User entered '30 Nov 2020 19:55:25'	System	01 Dec 2020 01:55:27
	System	01 Dec 2020 01:55:27

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-07T19:55:19', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1ca542d0-af7f-459f-995c-3c52acc47c3d' User entered 'No (N)'	System	08 Dec 2020 01:55:28

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-07T19:55:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1ca542d0-af7f-459f-995c-3c52acc47c3d' User entered 'No (N)'	System	08 Dec 2020 01:55:28

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-07T19:55:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '1ca542d0-af7f-459f-995c-3c52acc47c3d' User entered '07 Dec 2020 19:55:23'	System	08 Dec 2020 01:55:28
	System	08 Dec 2020 01:55:28

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-14T19:55:20', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '3ab36a94-cbe7-4b8a-b17c-42ffad814b73' User entered 'No (N)'	System	15 Dec 2020 01:55:30
	System	15 Dec 2020 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-14T19:55:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '3ab36a94-cbe7-4b8a-b17c-42ffad814b73' User entered 'No (N)'	System	15 Dec 2020 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-14T19:55:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '3ab36a94-cbe7-4b8a-b17c-42ffad814b73' User entered '14 Dec 2020 19:55:25'	System	15 Dec 2020 01:55:30
	System	15 Dec 2020 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-21T19:55:21', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a15afcd6-8151-4560-9ccf-f3b61f18f2f5'	System	22 Dec 2020 01:55:37
User entered 'No (N)'	System	22 Dec 2020 01:55:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-21T19:55:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a15afcd6-8151-4560-9ccf-f3b61f18f2f5'	System	22 Dec 2020 01:55:37
User entered 'No (N)'	System	22 Dec 2020 01:55:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-21T19:55:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a15afcd6-8151-4560-9ccf-f3b61f18f2f5' User entered '21 Dec 2020 19:55:26'	System	22 Dec 2020 01:55:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-28T21:48:48', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '639f196b-a9c8-4e63-a463-5faf0446c60f' User entered 'No (N)'	System	29 Dec 2020 03:48:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-28T21:48:53', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '639f196b-a9c8-4e63-a463-5faf0446c60f' User entered 'No (N)'	System	29 Dec 2020 03:48:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2020-12-28T21:48:56', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '639f196b-a9c8-4e63-a463-5faf0446c60f' User entered '28 Dec 2020 21:48:56'	System	29 Dec 2020 03:48:58
	System	29 Dec 2020 03:48:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-04T19:55:19', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '0faf2669-b566-433d-86d7-0a8d4c4b0849' User entered 'No (N)'	System	05 Jan 2021 01:55:30
	System	05 Jan 2021 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-04T19:55:22', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '0faf2669-b566-433d-86d7-0a8d4c4b0849' User entered 'No (N)'	System	05 Jan 2021 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-04T19:55:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '0faf2669-b566-433d-86d7-0a8d4c4b0849' User entered '04 Jan 2021 19:55:25'	System	05 Jan 2021 01:55:30
	System	05 Jan 2021 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-11T19:55:18', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '323d6c06-8fe0-4ffa-9d58-3e9bd9ef56ff' User entered 'No (N)'	System	12 Jan 2021 01:55:31

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-11T19:55:22', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '323d6c06-8fe0-4ffa-9d58-3e9bd9ef56ff'	System	12 Jan 2021 01:55:31
User entered 'No (N)'	System	12 Jan 2021 01:55:31

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-11T19:55:25', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '323d6c06-8fe0-4ffa-9d58-3e9bd9ef56ff' User entered '11 Jan 2021 19:55:25'	System	12 Jan 2021 01:55:31

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-18T19:55:51', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed9d664d-abea-4ab1-ac9c-119c7cf17db7'	System	19 Jan 2021 01:56:09
User entered 'No (N)'	System	19 Jan 2021 01:56:09

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-18T19:56:03', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed9d664d-abea-4ab1-ac9c-119c7cf17db7'	System	19 Jan 2021 01:56:09
User entered 'No (N)'	System	19 Jan 2021 01:56:09

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-18T19:56:06', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'ed9d664d-abea-4ab1-ac9c-119c7cf17db7'	System	19 Jan 2021 01:56:09
User entered '18 Jan 2021 19:56:06'	System	19 Jan 2021 01:56:09

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-25T19:55:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e4d99e3f-8528-492b-86fe-f8c6679b37d9' User entered 'No (N)'	System	26 Jan 2021 01:55:34
	System	26 Jan 2021 01:55:34

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-25T19:55:26', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e4d99e3f-8528-492b-86fe-f8c6679b37d9'	System	26 Jan 2021 01:55:34
User entered 'No (N)'	System	26 Jan 2021 01:55:34

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-01-25T19:55:29', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'e4d99e3f-8528-492b-86fe-f8c6679b37d9' User entered '25 Jan 2021 19:55:29'	System	26 Jan 2021 01:55:34
	System	26 Jan 2021 01:55:34

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-01T20:09:31', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'af964457-e886-4ad4-8521-ac4ccfd6b09d' User entered 'No (N)'	System	02 Feb 2021 02:13:15
	System	02 Feb 2021 02:13:15

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-01T20:09:33', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'af964457-e886-4ad4-8521-ac4ccfd6b09d'	System	02 Feb 2021 02:13:15
User entered 'No (N)'	System	02 Feb 2021 02:13:15

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-01T20:09:35', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'af964457-e886-4ad4-8521-ac4ccfd6b09d' User entered '01 Feb 2021 20:09:35'	System	02 Feb 2021 02:13:15
	System	02 Feb 2021 02:13:15

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-08T19:57:08', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'bce3c833-ce9b-4883-9028-20b7d8dbaea8' User entered 'No (N)'	System	09 Feb 2021 01:57:18
	System	09 Feb 2021 01:57:18

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-08T19:57:11', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'bce3c833-ce9b-4883-9028-20b7d8dbaea8' User entered 'No (N)'	System	09 Feb 2021 01:57:18

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-08T19:57:15', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'bce3c833-ce9b-4883-9028-20b7d8dbaea8' User entered '08 Feb 2021 19:57:15'	System	09 Feb 2021 01:57:18

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-15T19:55:19', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'fbe02f4a-2504-4a40-9da8-8616841c19d8' User entered 'No (N)'	System	16 Feb 2021 01:55:32
	System	16 Feb 2021 01:55:32

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-15T19:55:21', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'fbe02f4a-2504-4a40-9da8-8616841c19d8' User entered 'No (N)'	System	16 Feb 2021 01:55:32

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-15T19:55:27', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'fbc02f4a-2504-4a40-9da8-8616841c19d8'	System	16 Feb 2021 01:55:32
User entered '15 Feb 2021 19:55:27'	System	16 Feb 2021 01:55:32

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-22T19:55:21', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '22c5b52a-3644-49e5-b169-4a5ccfa28b76' User entered 'No (N)'	System	23 Feb 2021 01:55:30
	System	23 Feb 2021 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-22T19:55:23', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '22c5b52a-3644-49e5-b169-4a5ccfa28b76' User entered 'No (N)'	System	23 Feb 2021 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-02-22T19:55:27', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '22c5b52a-3644-49e5-b169-4a5ccfa28b76' User entered '22 Feb 2021 19:55:27'	System	23 Feb 2021 01:55:30
	System	23 Feb 2021 01:55:30

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-01T19:55:47-06:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '4cdd95e1-223e-433d-9439-77c7b91a067b'	System	02 Mar 2021 01:55:56
User entered 'No (N)'	System	02 Mar 2021 01:55:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-01T19:55:50-06:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '4cdd95e1-223e-433d-9439-77c7b91a067b'	System	02 Mar 2021 01:55:56
User entered 'No (N)'	System	02 Mar 2021 01:55:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-01T19:55:53-06:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '4cdd95e1-223e-433d-9439-77c7b91a067b'	System	02 Mar 2021 01:55:56
User entered '01 Mar 2021 19:55:53'	System	02 Mar 2021 01:55:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-08T20:24:27-06:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '0404b3f6-a3f1-4d08-83e3-3bca55eac797'	System	09 Mar 2021 02:33:24
User entered 'No (N)'	System	09 Mar 2021 02:33:24

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-08T20:24:33-06:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '0404b3f6-a3f1-4d08-83e3-3bca55eac797'	System	09 Mar 2021 02:33:24
User entered 'No (N)'	System	09 Mar 2021 02:33:24

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-08T20:24:39-06:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '0404b3f6-a3f1-4d08-83e3-3bca55eac797'	System	09 Mar 2021 02:33:24
User entered '08 Mar 2021 20:24:39'	System	09 Mar 2021 02:33:24

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-15T20:09:31-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a0ddb7-495e-4383-b223-d6160ed88df6'	System	16 Mar 2021 01:14:02
User entered 'No (N)'	System	16 Mar 2021 01:14:02

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-15T20:09:37-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a0ddb7-495e-4383-b223-d6160ed88df6'	System	16 Mar 2021 01:14:02
User entered 'No (N)'	System	16 Mar 2021 01:14:02

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-15T20:09:40-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'a0ddb7-495e-4383-b223-d6160ed88df6'	System	16 Mar 2021 01:14:02
User entered '15 Mar 2021 20:09:40'	System	16 Mar 2021 01:14:02

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-22T20:09:44-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '553599b7-e4b6-4999-844c-a99febb484c4' User entered 'Yes (Y)'	System	23 Mar 2021 01:13:56
	System	23 Mar 2021 01:13:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-22T20:09:47-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '553599b7-e4b6-4999-844c-a99febb484c4'	System	23 Mar 2021 01:13:56
User entered 'No (N)'	System	23 Mar 2021 01:13:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-22T20:09:55-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '553599b7-e4b6-4999-844c-a99febb484c4' User entered 'No (N)'	System	23 Mar 2021 01:13:56
	System	23 Mar 2021 01:13:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-22T20:10:01-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '553599b7-e4b6-4999-844c-a99febb484c4' User entered 'Yes (Y)'	System	23 Mar 2021 01:13:56
	System	23 Mar 2021 01:13:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Please 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-22T20:10:13-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '553599b7-e4b6-4999-844c-a99febb484c4'	System	23 Mar 2021 01:13:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Mar 2021 01:13:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-22T20:10:18-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '553599b7-e4b6-4999-844c-a99febb484c4'	System	23 Mar 2021 01:13:56
User entered '22 Mar 2021 20:10:18'	System	23 Mar 2021 01:13:56

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-29T19:58:35-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '327dafde-9ba3-4aaf-b6a9-6684a814e26e'	System	30 Mar 2021 00:58:47
User entered 'No (N)'	System	30 Mar 2021 00:58:47

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-29T19:58:39-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '327dafde-9ba3-4aaf-b6a9-6684a814e26e'	System	30 Mar 2021 00:58:47
User entered 'No (N)'	System	30 Mar 2021 00:58:47

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-29T19:58:42-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '327dafde-9ba3-4aaf-b6a9-6684a814e26e' User entered '29 Mar 2021 19:58:42'	System	30 Mar 2021 00:58:47
	System	30 Mar 2021 00:58:47

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-05T21:10:34-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '88bb89f1-2f93-44c5-a6aa-5aa8677b0dae' User entered 'No (N)'	System	06 Apr 2021 02:10:43
	System	06 Apr 2021 02:10:43

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-05T21:10:36-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '88bb89f1-2f93-44c5-a6aa-5aa8677b0dae'	System	06 Apr 2021 02:10:43
User entered 'No (N)'	System	06 Apr 2021 02:10:43

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-05T21:10:39-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '88bb89f1-2f93-44c5-a6aa-5aa8677b0dae'	System	06 Apr 2021 02:10:43
User entered '05 Apr 2021 21:10:39'	System	06 Apr 2021 02:10:43

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-12T20:09:47-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6e7dc95b-9e22-4a33-80b6-3d779a61bd7d' User entered 'No (N)'	System	13 Apr 2021 01:15:37
	System	13 Apr 2021 01:15:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-12T20:09:46-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6e7dc95b-9e22-4a33-80b6-3d779a61bd7d'	System	13 Apr 2021 01:15:37
User entered 'No (N)'	System	13 Apr 2021 01:15:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-12T20:09:51-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '6e7dc95b-9e22-4a33-80b6-3d779a61bd7d'	System	13 Apr 2021 01:15:37
User entered '12 Apr 2021 20:09:51'	System	13 Apr 2021 01:15:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-19T20:14:29-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23431001-d386-4784-bef6-5c7c491ae4e1'	System	20 Apr 2021 01:17:58
User entered 'Yes (Y)'	System	20 Apr 2021 01:17:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-19T20:14:33-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23431001-d386-4784-bef6-5c7c491ae4e1'	System	20 Apr 2021 01:17:58
User entered 'No (N)'	System	20 Apr 2021 01:17:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-19T20:14:37-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23431001-d386-4784-bef6-5c7c491ae4e1' User entered 'No (N)'	System	20 Apr 2021 01:17:58
	System	20 Apr 2021 01:17:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-19T20:14:43-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23431001-d386-4784-bef6-5c7c491ae4e1'	System	20 Apr 2021 01:17:58
User entered 'Yes (Y)'	System	20 Apr 2021 01:17:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Please 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-19T20:14:54-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23431001-d386-4784-bef6-5c7c491ae4e1'	System	20 Apr 2021 01:17:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Apr 2021 01:17:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-19T20:14:58-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '23431001-d386-4784-bef6-5c7c491ae4e1' User entered '19 Apr 2021 20:14:58'	System	20 Apr 2021 01:17:58
	System	20 Apr 2021 01:17:58

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-29T08:53:51-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '56010486-ec22-425c-8dd9-b60d1d11b8fe' User entered 'No (N)'	System	29 Apr 2021 13:54:06

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

Have you been exposed to someone with 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 (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-29T08:53:53-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '56010486-ec22-425c-8dd9-b60d1d11b8fe' User entered 'No (N)'	System	29 Apr 2021 13:54:06

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-04-29T08:53:55-05:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: '56010486-ec22-425c-8dd9-b60d1d11b8fe' User entered '29 Apr 2021 08:53:55'	System	29 Apr 2021 13:54:06
	System	29 Apr 2021 13:54:06

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 20:38:37

US3552240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:38:37
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 20:38:37

US3552240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:12:45

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:23:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-01T19:56:21-06:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'd88b9592-ff11-49b0-9335-fa2b328de931'	System	02 Mar 2021 01:56:28
User entered 'No (N)'	System	02 Mar 2021 01:56:28

US3552240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:12:45

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:23:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3BD076B-C029-42B3-9D00-916AE29B1F68)', Time: '2021-03-01T19:56:24-06:00', User OID: 'PatientReportedOutcome (US3552240)', ODM File OID: 'd88b9592-ff11-49b0-9335-fa2b328de931' User entered '01 Mar 2021 19:56:24'	System	02 Mar 2021 01:56:28
	System	02 Mar 2021 01:56:28

US3552240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:58:36

US3552240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '23 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:58:36

US3552240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:58:36

US3552240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:58:36

US3552240

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 17:57:14

US3552240

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:05
User entered 'l'	System	30 Dec 2020 17:57:14

US3552240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 17:57:23

US3552240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '30 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 17:57:23

US3552240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 17:57:23

US3552240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 17:57:23

US3552240

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Jan 2021 16:01:21

US3552240

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered 'l'	System	29 Jan 2021 16:01:21

US3552240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Jan 2021 16:01:29

US3552240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '29 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Jan 2021 16:01:29

US3552240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Jan 2021 16:01:29

US3552240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Jan 2021 16:01:29

US3552240

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Feb 2021 17:26:45

US3552240

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered 'l'	System	18 Feb 2021 17:26:45

US3552240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 18:41:15

US3552240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 18:41:15

US3552240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 18:41:15

US3552240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 18:41:15

US3552240

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 18:41:19

US3552240

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered 'l'	System	26 Feb 2021 18:41:19

US3552240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:30:18

US3552240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered '18 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:30:18

US3552240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[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 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:30:18

US3552240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered 'VISIT4'	System	18 Mar 2021 17:30:18

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:27:02
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:27:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:27:02
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered empty.	System	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:27:02
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:27:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:27:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:27:02
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered empty.	System	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:27:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered empty.	System	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:27:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered empty.	System	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:27:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered empty.	System	29 Mar 2021 21:03:01

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57

US3552240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57

US3552240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:30:23

US3552240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:30:23

US3552240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:30:33

US3552240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered '18 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:30:33

US3552240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered '11:37'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:30:33

US3552240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered '18 Mar 2021 11:37'	System	18 Mar 2021 17:30:33

US3552240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:31:05

US3552240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:29:57
User entered 'I'	System	18 Mar 2021 17:31:05

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:54:27

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '10:21'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:54:27

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '14 Jan 2021 10:21'	System	15 Jan 2021 19:54:27

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Safety Call (Safety Call)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:54:27

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:54:27

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Day 1 (Day 1)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '11 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '%'	System	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Mild (Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:08

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Day 2 (Day 2)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '%'	System	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Mild (Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:30

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Day 3 (Day 3)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '13 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '%'	System	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Mild (Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:55:46

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Day 4 (Day 4)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '%'	System	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Mild (Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Mild (Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User closed query 'Please verify is additional symptom days should be added. Were there any telemedicine calls completed on 17Jan, 18Jan, 19Jan? If yes, please update this form. Thank you! ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:21:41
Query 'Please verify is additional symptom days should be added. Were there any telemedicine calls completed on 17Jan, 18Jan, 19Jan? If yes, please update this form. Thank you! ' answered with 'no additional days as we received a negative result day of swab' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 20:03:03
User opened query 'Please verify is additional symptom days should be added. Were there any telemedicine calls completed on 17Jan, 18Jan, 19Jan? If yes, please update this form. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 22:38:53
User closed query 'Please update applicable eCRFs - symptom log past 15Jan, Covid diagnostic test if results are available, saliva eCRF> Thank you' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 22:38:53
Query 'Please update applicable eCRFs - symptom log past 15Jan, Covid diagnostic test if results are available, saliva eCRF> Thank you' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:00:28
User opened query 'Please update applicable eCRFs - symptom log past 15Jan, Covid diagnostic test if results are available, saliva eCRF> Thank you' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 22:41:22
User entered 'Day 5 (Day 5)'	Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '15 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	15 Jan 2021 19:56:57
User entered missing code ND - Not Done.	(b) (4)	
	Stanley Dublin (b) (4)	15 Jan 2021 19:56:31
	(b) (4)	

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '%'	System	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '96.9' F reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	15 Jan 2021 19:56:57
User entered missing code ND - Not Done.	(b) (4)	
	Stanley Dublin (b) (4)	15 Jan 2021 19:56:31
	(b) (4)	

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Mild (Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:56:31

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Day 6 (Day 6)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '16 Jan 2021'	(b) (4) Cassandra Zehenny (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '97'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '%'	System	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '97' F	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 18:01:15

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User closed query 'Please verify the test date and date of visit on this page. Illness visit took place on 15Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:21:27
Query 'Please verify the test date and date of visit on this page. Illness visit took place on 15Jan2021. ' answered with 'updated thank you' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:14:12
User entered '15 Jan 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:14:05
User opened query 'Please verify the test date and date of visit on this page. Illness visit took place on 15Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 22:36:07
User entered '22 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User entered '15 Jan 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:14:05
User entered '22 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '0'	System	26 Jan 2021 15:43:06

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:12:45

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:14:21

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '14 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:04

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '10:21'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:04

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '14 Jan 2021 10:21'	System	28 Jan 2021 15:16:04

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Safety Call (Safety Call)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:04

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:45

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:04

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '15 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '15 Jan 2021'	(b) (4) Cassandra Zehenny (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Saint Louis University's Vaccine Development Center'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:16:26

US3552240

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:45

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:27
User entered '0'	System	28 Jan 2021 15:16:26

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:12:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:12:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:12:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:12:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:12:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:12:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:12:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:12:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:12:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:12:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:12:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:12:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:12:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:12:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:12:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:12:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Cassandra Zehenny (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:12:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:12:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:12:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:12:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:12:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:43:24

US3552240

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:51:10

US3552240

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '15 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:51:10

US3552240

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Home (Home)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:51:10

US3552240

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User entered 'SICKD1'	System	15 Jan 2021 19:51:10

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '15 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '12:15'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User entered '15 Jan 2021 12:15'	System	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4)	15 Jan 2021 19:52:14
DataPoint set to visible.	(b) (4) System	15 Jan 2021 19:51:10

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4)	15 Jan 2021 19:52:14
DataPoint set to visible.	(b) (4) System	15 Jan 2021 19:51:10

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '96.9' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '64'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User entered 'bpm'	System	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '14'	Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User entered 'breaths/min'	System	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '126'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User entered 'mmHg'	System	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '84'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User entered 'mmHg'	System	15 Jan 2021 19:52:14

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43

US3552240

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43

US3552240

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:24

US3552240

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Jan 2021 19:52:24

US3552240

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:12:45

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 20:14:22

US3552240

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:12:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:43
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 15 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). Query 'Per Lab Recon: SARS-COV2: Sample dated 15 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with '1F60DNW' (Site from DM).	(b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4)	15 Feb 2021 18:22:34 03 Feb 2021 22:18:42
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 15 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). User entered '15 Jan 2021'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	29 Jan 2021 12:30:33 15 Jan 2021 20:14:22

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:00:03

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:00:03

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:00:03

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 18:00:03

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:00:00

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
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 18:00:00

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:24:00
User entered 'Placebo (Placebo)'	Stanley Doublin (b) (4) (b) (4)	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:24:00
User entered 'Placebo (Placebo)'	Stanley Doublin (b) (4)	07 Jan 2021 18:00:45
	(b) (4)	

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'I'	System	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'I'	System	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '77.5' in	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '273.6' lb	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered '32.09391'	System	07 Jan 2021 18:01:29
DataPoint set to visible.	System	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '77.5' in	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '273.6' lb	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered '32.09391'	System	07 Jan 2021 18:01:29
DataPoint set to visible.	System	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '10:32'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered '07 Jan 2021 10:32'	System	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '97.7' F	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '56'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'bpm'	System	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '16'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'breaths/min'	System	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '119'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'mmHg'	System	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '84'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'mmHg'	System	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '77.5' in	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '273.6' lb	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:01:29

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered '32.09391'	System	07 Jan 2021 18:01:29
DataPoint set to visible.	System	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '10:55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered '07 Jan 2021 10:55'	System	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '98' F	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '71'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'bpm'	System	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '16'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'breaths/min'	System	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '125'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'mmHg'	System	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '75'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'mmHg'	System	07 Jan 2021 18:02:08

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:20

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:20

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'mRNA-1273'	System	07 Jan 2021 18:02:46
DataPoint set to visible.	System	07 Jan 2021 18:00:45

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered '10:55'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered '07 Jan 2021 10:55'	System	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'ONCE'	System	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'INTRAMUSCULAR'	System	07 Jan 2021 18:02:46

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:03:05

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:03:05

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '10:15'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:03:05

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered '07 Jan 2021 10:15'	System	07 Jan 2021 18:03:05

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:03:48

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '07 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:03:48

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '10:20'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Jan 2021 18:03:48

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:45

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered '07 Jan 2021 10:20'	System	07 Jan 2021 18:03:48

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 17:30:05

US3552240

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:47
User entered 'I'	System	14 Jan 2021 17:30:05

US3552240

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 17:30:14

US3552240

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 17:30:14

US3552240

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 17:30:14

US3552240

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Doublin (b) (4)	14 Jan 2021 17:30:14

US3552240

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:25:49

US3552240

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User entered 'l'	System	04 Feb 2021 20:25:49

US3552240

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User entered 'I'	System	04 Feb 2021 20:25:49
DataPoint set to visible.	System	04 Feb 2021 20:25:49

US3552240

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:00

US3552240

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:00

US3552240

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 20:26:00

US3552240

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'OLD29'	System	04 Feb 2021 20:26:00

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '11:29'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered '04 Feb 2021 11:29'	System	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '97.8' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '67'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'bpm'	System	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'breaths/min'	System	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '133'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'mmHg'	System	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '87'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'mmHg'	System	04 Feb 2021 20:26:28

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '12:21'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered '04 Feb 2021 12:21'	System	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '97.8' F reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	04 Feb 2021 20:50:48
User entered '99.8' F	(b) (4)	
	Stanley Dublin (b) (4)	04 Feb 2021 20:26:58
	(b) (4)	

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '78'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'bpm'	System	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'breaths/min'	System	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '132'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'mmHg'	System	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '90'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'mmHg'	System	04 Feb 2021 20:26:58

US3552240

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:28:00

US3552240

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:28:00

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

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)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'mRNA-1273'	System	04 Feb 2021 20:28:25
DataPoint set to visible.	System	04 Feb 2021 20:25:49

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '11:51'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered '04 Feb 2021 11:51'	System	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'ONCE'	System	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 20:28:25

US3552240

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:46:18

US3552240

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:51
User entered 'l'	System	11 Feb 2021 17:46:18

US3552240

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:46:27

US3552240

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered '11 Feb 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:46:27

US3552240

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:23:09
User entered 'Contact Made (CONTACT MADE)'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:46:27

US3552240

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:23:09
User entered empty.	(b) (4) Heather Douds (b) (4)	11 Feb 2021 17:46:27

US3552240

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:19
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	26 Feb 2021 20:51:39

US3552240

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:19
User entered 'l'	System	26 Feb 2021 20:51:39

US3552240

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:28

US3552240

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered '18 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:28

US3552240

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	18 Mar 2021 17:29:28

US3552240

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User entered 'OLD57'	System	18 Mar 2021 17:29:28

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User entered empty.	System	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User entered empty.	System	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User entered empty.	System	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User entered empty.	System	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User entered empty.	System	18 Mar 2021 17:29:34

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45

US3552240

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45

US3552240

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:39

US3552240

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:39

US3552240

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:49

US3552240

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered '18 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:49

US3552240

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:51
User entered '11:37'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Mar 2021 17:29:49

US3552240

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:45
User entered '18 Mar 2021 11:37'	System	18 Mar 2021 17:29:49

US3552240

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:12:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:28
DataPoint Verified.		12 Apr 2021 18:14:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:05:57

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:34
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 02:58:51
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'No other respiratory virus or infection identified, and thus cannot be combined' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Feb 2021 21:12:08
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:31:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 15:14:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 15:14:04
Data point term sent to Coder	System	20 Jan 2021 15:13:37
User entered 'cough'	Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:36
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:37
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:39
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:41
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '14 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:42
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
User entered empty.	System	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:45
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:46
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '14 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:49
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
User entered empty.	System	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:51
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:52
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:54
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:56
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:58
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:21:59
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:01
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:02
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:04
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:06
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:07
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 16:22:09
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:11
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:13
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:15
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'None (NONE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:16
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:18
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:19
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:21
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:23
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
DataPoint Un-verified.		01 Apr 2021 16:22:25
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
User entered '0'	System	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14
User entered 'I'	System	20 Jan 2021 15:13:12

US3552240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:14

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:29
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Jan 2021 15:30:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 15:30:04
Data point term sent to Coder	System	20 Jan 2021 15:14:39
User entered 'rhinorrhea'	Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:31
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:33
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:38
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:39
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '11 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:41
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
User entered empty.	System	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:42
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:44
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '14 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:45
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
User entered empty.	System	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:47
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:49
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:50
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:52
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:53
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:55
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:57
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:58
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:22:59
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:01
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:03
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:04
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:06
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:07
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:09
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'None (NONE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:11
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:12
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:14
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:16
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:17
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
DataPoint Un-verified.		01 Apr 2021 16:23:19
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
User entered '0'	System	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17
User entered 'I'	System	20 Jan 2021 15:14:08

US3552240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:17

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:23:27
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 15:18:04
Data point term sent to Coder	System	20 Jan 2021 15:16:41
User entered 'fatigue'	Mikayla Frye (b) (4)	20 Jan 2021 15:16:14
	(b) (4)	

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:23:29
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:23:30
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:23:32
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:23:33
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '16 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:13
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
User entered empty.	System	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:15
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)' reason for change: New Information	(b) (4) Mikayla Frye (b) (4)	29 Jan 2021 16:03:25
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:16
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '22 Jan 2021' reason for change: New Information	(b) (4) Mikayla Frye (b) (4)	29 Jan 2021 16:03:25
User entered empty.	(b) (4) Mikayla Frye (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:18
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
User entered empty.	System	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:20
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:21
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:23
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:24
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:26
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:28
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:30
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:32
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:33
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:36
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:37
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:39
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:41
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:42
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:44
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'None (NONE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:46
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:47
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:49
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:50
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Jan 2021 16:03:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:52
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
DataPoint Un-verified.		01 Apr 2021 16:25:54
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
User entered '0'	System	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20
User entered 'I'	System	20 Jan 2021 15:16:14

US3552240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:20

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 16:25:59
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 02:59:23
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'Not an exacerbation' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Feb 2021 21:12:45
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:31:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 15:19:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 15:19:05
Data point term sent to Coder	System	20 Jan 2021 15:17:41
User entered 'nasal congestion'	Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:01
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:03
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:04
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 16:26:06
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '16 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:07
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
User entered empty.	System	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:09
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)' reason for change: New Information	(b) (4) Mikayla Frye (b) (4)	29 Jan 2021 16:03:44
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:11
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '22 Jan 2021' reason for change: New Information	(b) (4) Mikayla Frye (b) (4)	29 Jan 2021 16:03:44
User entered empty.	(b) (4) Mikayla Frye (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:12
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
User entered empty.	System	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:14
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:15
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:17
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:18
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:20
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:22
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:23
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:25
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:27
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:29
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:31
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:33
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:35
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:37
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Related (RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:38
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'None (NONE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:39
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:41
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:43
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:44
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Jan 2021 16:03:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:46
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
DataPoint Un-verified.		01 Apr 2021 16:26:47
DataPoint Verified.		01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
User entered '0'	System	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23
User entered 'I'	System	20 Jan 2021 15:16:53

US3552240

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:23:23

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:15
User entered	System	25 Mar 2021 13:25:11
'USA-US089-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	25 Mar 2021 13:25:11

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Hashimoto's disease - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 18:56:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 18:56:40
Data point term sent to Coder	System	23 Mar 2021 18:40:20
Coding entries removed.	Cassandra Zehenny (b) (4)	23 Mar 2021 18:39:33
Signature has been broken.	(b) (4)	
User entered 'HASHIMOTO'S DISEASE' reason for change: New Information	Cassandra Zehenny (b) (4)	23 Mar 2021 18:39:33
User signature succeeded.	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	05 Feb 2021 18:09:55
User entered 'hypothyroidism'	Coder Import (b) (4)	05 Feb 2021 18:09:55
	System	05 Feb 2021 18:09:04
	Stanley Dublin (b) (4)	05 Feb 2021 18:08:53
	(b) (4)	

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'AE hypothyroidism was previously reported w start date 02Feb2021. Please verify is SAE hashimoto's disease start date should be 19Mar2021 (TSH high / TPO a present/ change of meds) , and AE hypothyroidism should be captured separately with start date 02Feb2021 and end date 19Mar2021. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 17:01:01
Query 'AE hypothyroidism was previously reported w start date 02Feb2021. Please verify is SAE hashimoto's disease start date should be 19Mar2021 (TSH high / TPO a present/ change of meds) , and AE hypothyroidism should be captured separately with start date 02Feb2021 and end date 19Mar2021. Thank you! ' answered with 'Hashimoto's disease is the cause for the hypothyroidism, data is correct as entered' (Site from CRA).	Heather Douds (b) (4) (b) (4)	01 Apr 2021 18:27:39
User opened query 'AE hypothyroidism was previously reported w start date 02Feb2021. Please verify is SAE hashimoto's disease start date should be 19Mar2021 (TSH high / TPO a present/ change of meds) , and AE hypothyroidism should be captured separately with start date 02Feb2021 and end date 19Mar2021. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 17:00:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 13:46:34
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. ' answered with 'this is the reported date that subject started to experience symptoms' (Site from Safety).	Cassandra Zehenny (b) (4)	06 Apr 2021 15:39:45
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:28:29
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '02 Feb 2021'	(b) (4) Stanley Doublin (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User entered empty.	sharon frey (b) (4)	26 Feb 2021 03:26:46
	(b) (4)	
	Stanley Dublin (b) (4)	05 Feb 2021 18:08:53
	(b) (4)	

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 15:05:44
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 15:05:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	05 Feb 2021 18:08:53
	(b) (4)	

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 15:05:44
User entered '1' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 15:05:44
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4)	
	Stanley Dublin (b) (4)	05 Feb 2021 18:08:53
	(b) (4)	

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 13:46:40
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug. ' answered with 'related because other cause is unknown at this time. ' (Site from Safety).	Cassandra Zehenny (b) (4)	06 Apr 2021 19:12:16
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:29:19
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	24 Mar 2021 20:15:31
	(b) (4)	
User entered 'Related (RELATED)' reason for change: New Information	Heather Douds (b) (4)	24 Mar 2021 20:15:31
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	26 Feb 2021 03:26:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4)	05 Feb 2021 18:08:53
	(b) (4)	

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [07 Jan 2021], then event occurred).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:54
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [07 Jan 2021], then event occurred).' answered with 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 18:13:18
Signature has been broken.	Cassandra Zehenny (b) (4)	12 Apr 2021 14:03:33
User entered 'None (NONE)' reason for change: Per Query Resolution	(b) (4)	
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [07 Jan 2021], then event occurred).' (Site from Safety). DataPoint Verified.	Cassandra Zehenny (b) (4)	12 Apr 2021 14:03:21
User signature succeeded.	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4)	12 Apr 2021 14:03:21
	(b) (4), (b) (6)	12 Apr 2021 13:07:07
	(b) (4), (b) (6)	01 Apr 2021 16:21:15
	sharon frey (b) (4)	26 Feb 2021 03:26:46
	(b) (4)	
	Stanley Dublin (b) (4)	05 Feb 2021 18:08:53
	(b) (4)	

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 18:29:05
User signature succeeded.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:46
User closed query 'PV Query: Please provide date and relevant test results for routine labs performed through PCP. If unknown, please indicate so' (Site from Safety).	(b) (4)	07 Apr 2021 13:46:43
Query 'PV Query: Please provide date and relevant test results for routine labs performed through PCP. If unknown, please indicate so' answered with 'updated' (Site from Safety).	Cassandra Zehenny (b) (4)	06 Apr 2021 19:14:17
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	06 Apr 2021 19:14:11
Signature has been broken.	Cassandra Zehenny (b) (4)	06 Apr 2021 19:14:11
User entered 'SUBJECT HAD ROUTINE LABS THROUGH PCP AND FOUND TO HAVE a HIGH thyroid stimulating hormone with a result of 8.613 on 02Feb. DEVELOPED SYMPTOMS OF HAIR LOSS AND JOINT ACHES AND THEN DIAGNOSED WITH HASHIMOTO'S DISEASE. PRESCRIBED SYNTHROID 75 MCG DAILY.' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	06 Apr 2021 19:14:11
User opened query 'PV Query: Please provide date and relevant test results for routine labs performed through PCP. If unknown, please indicate so' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:29:29
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4)	24 Mar 2021 15:07:48
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Mar 2021 15:07:48
Signature has been broken.	Cassandra Zehenny (b) (4)	24 Mar 2021 15:07:48

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'subject had routine labs through PCP and found to have low thyroid hormone. developed symptoms of hair loss and joint aches and then diagnosed with Hashimoto's disease. Prescribed synthroid 75 mcg daily.' reason for change: New Information	Cassandra Zehenny (b) (4)	24 Mar 2021 15:07:48
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Mar 2021 15:05:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:46
User entered empty.	(b) (4) Stanley Dublin (b) (4)	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 15:05:44
User entered '0'	System	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:12:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Feb 2021 18:08:53

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:55:43
Query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'unknown at this time' (Site from DM).	Cassandra Zehenny (b) (4)	05 Apr 2021 16:17:09
User opened query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:13:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 16:35:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 16:35:27
Data point term sent to Coder	System	26 Mar 2021 16:34:48
User entered 'thyroid nodules'	Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '16 Feb 2021'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:57:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:27:02
Signature has been broken.	(b) (4) Heather Douds (b) (4)	29 Mar 2021 17:18:07
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4) Heather Douds (b) (4)	29 Mar 2021 17:18:07
User signature succeeded.	(b) (4) sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:21:15
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:12:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Mar 2021 16:33:57

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Peroneal tendonitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 12:24:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 12:24:04
Data point term sent to Coder	System	20 Apr 2021 14:01:51
User entered 'left peroneal tendonitis'	Cassandra Zehenny (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '20 Feb 2021'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'I'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:29:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 14:01:06

US3552240

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:12:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	20 Apr 2021 14:01:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:12:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:28
DataPoint Verified.		21 Apr 2021 03:27:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 12:52:25

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:53:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 12:53:46
Data point term sent to Coder	System	31 Aug 2020 12:53:22
User entered 'zyrtec'	Stanley Doublin (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'seasonal allergies'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM). Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM). User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM). User entered 'I'	(b) (4) (b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6) Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 04:37:41 13 Oct 2020 20:35:59 13 Oct 2020 18:08:35 31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'tablet (TABLET)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'as needed (PRN)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'un Jul 2019'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 12:53:22

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
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: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Aug 2020 12:54:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 12:54:52
Data point term sent to Coder	System	31 Aug 2020 12:54:23
User entered 'naproxen'	Stanley Doublin (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'low back pain'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '500'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'as needed (PRN)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'un UNK 2012'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 12:53:58

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Sep 2020 23:37:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 23:37:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:56:51
Data point term sent to Coder	System	31 Aug 2020 12:55:23
User entered 'vitamin D'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4) Cassandra Zehenny (b) (4)	11 Nov 2020 15:12:55
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'health'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '3000'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'IU (IU)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'un Jun 2020'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 12:54:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 15:43:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 15:43:30
Data point term sent to Coder	System	31 Aug 2020 12:57:25
User entered 'toradol'	Stanley Doublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Left ankle sprain'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '30'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'once (ONCE)'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '03 Aug 2020'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '0'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '03 Aug 2020'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User entered empty.	System	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User entered empty.	System	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:33
User entered empty.	System	31 Aug 2020 12:57:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:04:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:04:08
Data point term sent to Coder	System	23 Nov 2020 20:02:37
Coding entries removed.	Stanley Dublin (b) (4)	23 Nov 2020 20:02:07
Coding entries removed.	Stanley Dublin (b) (4)	23 Nov 2020 20:02:07
User entered 'influenza vaccine' reason for change: Data Entry Error	Stanley Dublin (b) (4)	23 Nov 2020 20:02:07
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)	08 Oct 2020 23:54:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:54:59
Data point term sent to Coder	System	08 Oct 2020 17:57:56
Coding entries removed.	Stanley Dublin (b) (4)	08 Oct 2020 17:57:10
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)	01 Oct 2020 19:33:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 19:33:57
Data point term sent to Coder	System	01 Oct 2020 19:33:09
Data point term sent to Coder	System	01 Oct 2020 19:32:08
User entered 'flu shot'	Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

2441 of 2607

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'influenza PROPHYLAXIS' reason for change: Data Entry Error	Stanley Dublin (b) (4)	23 Nov 2020 20:02:07
User entered 'Prophylaxis' reason for change: Data Entry Error	Stanley Dublin (b) (4)	08 Oct 2020 17:57:10
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:32:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 19:32:25
User entered 'flu prevention' reason for change: Data Entry Error	Stanley Dublin (b) (4)	01 Oct 2020 19:32:25
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:32:02
User entered empty.	Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User closed query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs. ' (Site from DM).	(b) (4), (b) (6)	Jan 2021 06:48:40
Query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs. ' answered with 'Data is not unknown; data is correct as entered.' (Site from DM).	Heather Douds (b) (4) (b) (4)	25 Jan 2021 21:08:12
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)	25 Jan 2021 11:07:49
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).		25 Jan 2021 11:07:49
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 'subject reported data, exact dosage unknown.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	22 Jan 2021 19:19:20
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).	(b) (4), (b) (6)	21 Jan 2021 08:41:36
User entered 'I'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Other (OTHER)'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'cc'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'once (ONCE)'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '15 Sep 2020'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '0'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '15 Sep 2020'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User entered empty.	System	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User entered empty.	System	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:35
User entered empty.	System	01 Oct 2020 19:32:02

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN EXTRA STRENGTH - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 00:22:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 00:22:34
Data point term sent to Coder	System	14 Oct 2020 15:18:47
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	14 Oct 2020 15:17:50
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'Updated' (Site from System).	Cassandra Zehenny (b) (4)	14 Oct 2020 15:17:50
Data point term sent to Coder	System	14 Oct 2020 15:17:46
User entered 'EXCEDRIN ES [Acetaminophen 250mg, Aspirin 250 mg, Caffeine 65 mg]' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	14 Oct 2020 15:17:43
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	14 Oct 2020 09:58:22
Data point term sent to Coder	System	08 Oct 2020 17:58:58
User entered 'excedrin ES'	Stanley Doublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 13:12:36
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'within 7 day post-injection period, therefore AR, not AE' (Site from DM).	Cassandra Zehenny (b) (4)	10 Dec 2020 16:32:27

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'l'	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'tablet (TABLET)'	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'once (ONCE)'	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	10 Nov 2020 19:18:20
User entered '7 Oct 2020'	(b) (4)	
	Stanley Dublin (b) (4)	08 Oct 2020 17:58:10
	(b) (4)	

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '0'	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	Stanley Dublin (b) (4)	10 Nov 2020 19:18:20
User entered '7 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	08 Oct 2020 17:58:19
User entered empty.	Stanley Dublin (b) (4)	08 Oct 2020 17:58:19
	(b) (4)	
	Stanley Dublin (b) (4)	08 Oct 2020 17:58:10
	(b) (4)	

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Headaches part of medical history' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:06:03
	Cassandra Zehenny (b) (4)	03 Nov 2020 15:33:05

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 11:50:38
	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User entered empty.	System	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User entered empty.	System	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:39
User entered empty.	System	08 Oct 2020 17:58:10

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: MOMETASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 16:39:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 16:39:34
Data point term sent to Coder	System	22 Oct 2020 16:28:46
User entered 'mometasone'	Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ECZEMA worsened. If yes, please review if an AE of worsening corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.	(b) (4), (b) (6)	14 Dec 2020 11:13:37
' (Site from DM).		
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ECZEMA worsened. If yes, please review if an AE of worsening corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.	Cassandra Zehenny (b) (4)	10 Dec 2020 16:32:46
' answered with 'Not worsening, typical eczema symptoms and treatment' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ECZEMA worsened. If yes, please review if an AE of worsening corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.	(b) (4), (b) (6)	10 Dec 2020 08:02:22
' (Site from DM).		
User entered 'eczema'	Mikayla Frye (b) (4)	22 Oct 2020 16:28:09
	(b) (4)	

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'l'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Other (OTHER)'	Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'application'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'twice daily (BID)'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Topical (TOPICAL)'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '20 Oct 2020'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '0'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)' reason for change: New Information	(b) (4) Mikayla Frye (b) (4)	30 Oct 2020 17:44:04
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '22 Oct 2020' reason for change: New Information	Mikayla Frye (b) (4)	30 Oct 2020 17:44:04
User entered empty.	Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4)	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User entered '2'	System	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User entered 'I'	System	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:41
User entered '804 (804)'	System	22 Oct 2020 16:28:09

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.	(b) (4)	01 Apr 2021 16:53:29
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:42:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:42:41
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:22 23 Mar 2021 18:40:41
User signature succeeded.	(b) (4) sharon frey (b) (4) (b) (4)	21 Feb 2021 18:22:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:31:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:31:27
Data point term sent to Coder User entered 'synthroid'	System Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 20:30:20 04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	23 Mar 2021 18:40:41
	(b) (4)	
User entered 'hashimoto's disease' reason for change: New Information	Cassandra Zehenny (b) (4)	23 Mar 2021 18:40:41
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
	(b) (4)	
User entered 'hypothyroidism'	Stanley Dublin (b) (4)	04 Feb 2021 20:29:31
	(b) (4)	

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '25'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'ug (ug)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '03 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Signature has been broken.	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:40:41
User entered 'No (N)' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:40:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Signature has been broken.	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:40:41
User entered '18 Mar 2021' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:40:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered empty.	(b) (4) Stanley Dublin (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
DataPoint Verified.		01 Apr 2021 16:53:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
User entered 'I'	System	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
User entered '1'	System	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:31:47
User entered '804 (804)'	System	04 Feb 2021 20:29:31

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Mar 2021 19:13:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:13:40
Data point term sent to Coder	System	23 Mar 2021 18:41:22
User entered 'synthroid'	Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'hashimoto's disease'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '75'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'ug (ug)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'once daily (QD)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Oral (ORAL)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '19 Mar 2021'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:31
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 18:41:06

US3552240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:12:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:28
DataPoint Verified.	(b) (4)	12 Apr 2021 18:15:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	26 Mar 2021 16:32:35
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	26 Mar 2021 16:32:35
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:22:47
	(b) (4)	
User entered 'No (N)'	Heather Douds (b) (4)	18 Feb 2021 17:26:56
	(b) (4)	

US3552240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '04 Mar 2021'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:32:58

US3552240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'needle aspiration of thyroid nodule'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:32:58

US3552240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'Adverse Event (AE)'	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:32:58

US3552240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:45

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:53:48
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	26 Mar 2021 16:32:58

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'USA-US089-2021-MRNA-1273-P301000006'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'No (N)'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'sharon'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'frey'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:49:28
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:54
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:05:57

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:49:30
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:56
User entered 'Saint Louis'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:05:57

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'MO'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:32
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:57
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:48:20
DataPoint Verified.		01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'US'	(b) (4) System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 13:25:49
User entered '2'	System	07 Apr 2021 13:46:58
User entered '1'	System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'USA-US089-2021-MRNA-1273-P301000006'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'No (N)'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'Yes (Y)'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'sharon'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'frey'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:28
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:54
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:30
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:56
User entered 'Saint Louis'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'MO'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:32
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:57
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:48:20
DataPoint Verified.		01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'US'	(b) (4) System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 13:25:49
User entered '2'	System	07 Apr 2021 13:46:58
User entered '1'	System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:12:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered '25/Mar/2021 08:25'	(b) (4) System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:12:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:48:20
DataPoint Verified.		01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'l'	(b) (4), (b) (6)	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'USA-US089-2021-MRNA-1273-P301000006'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'No (N)'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'Yes (Y)'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'sharon'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'frey'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:28
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:54
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:30
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:56
	(b) (4)	
User entered 'Saint Louis'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'MO'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:32
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:57
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:48:20
DataPoint Verified.		01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'US'	(b) (4) System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 13:25:49
User entered '2'	System	07 Apr 2021 13:46:58
User entered '1'	System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:12:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:20:00
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:45
User entered '07/Apr/2021 09:46'	(b) (4) System	07 Apr 2021 13:46:58

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:12:45

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)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:20:00
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 13:48:20
User entered 'l'		07 Apr 2021 13:46:58

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'USA-US089-2021-MRNA-1273-P301000006'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'No (N)'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'No (N)'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'No (N)'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'sharon'	(b) (4), (b) (6)	25 Mar 2021 13:25:11
	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 13:25:29
User entered 'frey'	System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:28
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:54
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:30
DataPoint Un-verified.		13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:56
User entered 'Saint Louis'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
Reviewed for Safety.	(b) (4)	25 Mar 2021 13:25:29
User entered 'MO'	(b) (4), (b) (6) System	25 Mar 2021 13:25:11

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:49:32
DataPoint Un-verified.	System	13 Apr 2021 13:25:49
User entered empty.	System	13 Apr 2021 13:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:19:57
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 15:05:57
	(b) (4)	

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:48:20
DataPoint Verified.		01 Apr 2021 16:03:23
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:19
User entered 'US'	(b) (4) System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 13:25:49
User entered '2'	System	07 Apr 2021 13:46:58
User entered '1'	System	25 Mar 2021 13:25:34

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:12:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:49:38
User entered '13/Apr/2021 06:25'	System	13 Apr 2021 13:25:49

US3552240

Folder: SAE USA-US089-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:12:45

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)	16 Apr 2021 18:02:43
DataPoint Verified.	(b) (4)	14 Apr 2021 15:49:38
User entered 'l'	(b) (4), (b) (6)	13 Apr 2021 13:25:49