US3552273 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:52:44

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US3552273

Form: Participant Creation

Data signed: (b) (4) **21 Feb 2021 18:33:42**

Generated On: 11 Aug 2021 22:52:44

Participant ID	US3552273

mRNA-1273-P301 Completion Guidelines

US3552273

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3552273

Folder: Screening

Form: Demographics

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female ○
	Male ●

Ethnicity	Hispanic or Latino ○
	Not Hispanic or Latino ●
	Not Reported ○
	Unknown ○

Race (Check All That Apply)

White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Date of Informed Consent *(dd MMM yyyy)*	01 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020

Protocol Version	
	Amendment 1 ◯
	Amendment 2 ◯
	Amendment 3 ●
	Amendment 4 ◯
	Amendment 5 ◯

Was participant enrolled in the study?	Yes ●
	No ◯

If No, indicate reason for screen fail	Withdrew Consent ◯
	Inclusion/Exclusion ◯
	Cohort Full ◯
	Other ◯

If reason for screen fail is Other, specify	

Was this participant screened previously?	Yes ◯
	No ●

If Yes, previous participant number	
Enrollment Trigger	1

US3552273

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Did the participant meet all eligibility criteria?   Yes ●

                                                                              No ◯

Were any significant conditions reported?   Yes ●
                                                        No ◯

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

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

US3552273

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3552273

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Condition	GENERAL ANXIETY DISORDER
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3552273

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN APR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN APR 2009
Stop date completely unknown	False
Start Month and Year (derived)	APR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	APR 2009
Stop Year (derived)	2009

US3552273

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Condition	RENAL CALCULI
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬭
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3552273

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

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

US3552273

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 18:34:06

Generated On: 11 Aug 2021 22:52:44

Condition	LITHOTRIPSY
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3552273
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **21 Feb 2021 18:34:07**
Generated On: 11 Aug 2021 22:52:44

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	01 SEP 2020
Time of assessment *(00:00-23:59)*	12:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:00
Height *(xxx.x)*	69 in
Weight *(xxx.x)*	185.6 lb
BMI *(xxx.x)*	27.46564 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
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)	

US3552273

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   01 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **21 Feb 2021 18:34:07**

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ○ No ●
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ○ No ●
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ○ No ●
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ○ No ●
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ○ No ●
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ○ No ●
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ○ No ●
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ○ No ●
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ○ No ●
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ○ No ●
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ○ No ●
Other	Yes ● No ○

Specify

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

FLEW 6 WEEKS AGO AND GOES
TO THE (b) (6) TO SEE
STAFF WITH MASK TWICE A
MONTH FOR 2 DAYS, WORK
PRIMARILY FROM HOME,
GROCERY SHOPPING ONCE A
WEEK, ONE ON ONE PERSON
TRAINER IN PUBLIC GYM

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

What was the date of randomization? *(dd MMM yyyy)*	01 SEP 2020
What was the participant's randomization number?	110608

In what Cohort was the participant enrolled?

- >=18 and <65 years and not at risk ●
- >=18 and <65 years and at risk ○
- >=65 years ○

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ○ No ●
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ○ No ●
Severe obesity (body mass index > or = 40kg/m2	Yes ○ No ●
Diabetes (Type I, Type 2, or gestational)	Yes ○ No ●
Liver Disease	Yes ○ No ●
Human Immunodeficiency Virus (HIV) infection	Yes ○ No ●

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	01 SEP 2020
Time of assessment *(00:00-23:59)*	12:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:00
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	01 SEP 2020
Time of assessment *(00:00-23:59)*	14:07 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:07
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	124 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	177 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	105 mmHg
Diastolic Blood Pressure units	MMHG

US3552273

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

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.

Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **21 Feb 2021 18:34:07**
Generated On: 11 Aug 2021 22:52:44

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 SEP 2020
What was the treatment time? *(00:00-23:59)*	13:37 (24 HR)
Treatment Date and Time (derived)	01 SEP 2020 13:37
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	01 SEP 2020
Collection time *(00:00-23:59)*	13:00 (24 HR)
Collection date and time (derived)	01 SEP 2020 13:00

US3552273

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **21 Feb 2021 18:34:07**
Generated On: 11 Aug 2021 22:52:44

Collection date *(dd MMM yyyy)*			01 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:12	01 SEP 2020 13:12
Nasopharyngeal Swab 2	No		

US3552273
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **21 Feb 2021 18:34:07**
Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

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**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	01 SEP 2020 16:15
PC Open Date & Time	01 SEP 2020 13:57
PC Close Date & Time	01 SEP 2020 16:27

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °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	02 SEP 2020 10:56
PC Open Date & Time	01 SEP 2020 17:22
PC Close Date & Time	02 SEP 2020 11:59

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °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	02 SEP 2020 22:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

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**	96.0 °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	03 SEP 2020 21:30
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °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	04 SEP 2020 17:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

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	05 SEP 2020 21:42
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-2713117

TIMEPOINT	DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯

Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 SEP 2020 18:51
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

TIMEPOINT	DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

| Was **TEMPERATURE** taken? | Yes ● |
| | No ○ |

Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	07 SEP 2020 21:25
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

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 SEP 2020 16:13
PC Open Date & Time	01 SEP 2020 13:57
PC Close Date & Time	01 SEP 2020 16:27

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

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	02 SEP 2020 10:56
PC Open Date & Time	01 SEP 2020 17:22
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-2713121

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 2
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	02 SEP 2020 22:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 3
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	03 SEP 2020 18:59
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-2713123

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 4
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	04 SEP 2020 17:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 5
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	05 SEP 2020 17:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 6
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	06 SEP 2020 18:38
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 7
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	07 SEP 2020 17:19
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:52:44

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 ◯

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	01 SEP 2020 16:13
PC Open Date & Time	01 SEP 2020 13:57
PC Close Date & Time	01 SEP 2020 16:27

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

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

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○

PC Time stamp	02 SEP 2020 10:06
PC Open Date & Time	01 SEP 2020 17:22
PC Close Date & Time	02 SEP 2020 11:59

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:52:44

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 ●

	Yes ◯
PC Time stamp	02 SEP 2020 22:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:52:44

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 ●

Yes ◯

PC Time stamp	03 SEP 2020 18:59
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 4

HEADACHE

- ○ None
- ● No interference with activity
- ○ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- ○ Any use of prescription pain reliever or prevents daily activity

FATIGUE

- ● None
- ○ No interference with activity
- ○ Some interference with activity
- ○ Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- ● None
- ○ No interference with activity
- ○ Some interference with activity
- ○ Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- ● None
- ○ No interference with activity
- ○ Some interference with activity
- ○ Significant; prevents daily activity

NAUSEA/VOMITING

- ● None
- ○ No interference with activity or 1-2 episodes/24 hours
- ○ Some interference with activity or >2 episodes/24 hours
- ○ Prevents daily activity, requires outpatient IV hydration

CHILLS

- ● None
- ○ No interference with activity
- ○ Some interference with activity not requiring medical attention
- ○ Prevents daily activity and requires medical attention

Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? ● No

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US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:52:44

	Yes ◯
PC Time stamp	04 SEP 2020 17:15
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:52:44

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 ●

	Yes ◯
PC Time stamp	05 SEP 2020 17:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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 ⬤

FDA-CBER-2022-1614-2713140

Yes ◯

PC Time stamp	06 SEP 2020 18:38
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:52:44

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 ⚫

	Yes ◯
PC Time stamp	07 SEP 2020 17:19
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **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 ◯

PC Time Stamp	08 SEP 2020 15:50
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	08 SEP 2020 15:50
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 08 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3552273
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **21 Feb 2021 18:34:06**
Generated On: 11 Aug 2021 22:52:44

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 15 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3552273
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **21 Feb 2021 18:34:06**
Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3552273
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **21 Feb 2021 18:34:06**
Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3552273
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **21 Feb 2021 18:34:07**
Generated On: 11 Aug 2021 22:52:44

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT2

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	28 SEP 2020
Time of assessment *(00:00-23:59)*	09:02 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:02
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	140 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	98 mmHg
Diastolic Blood Pressure units	MMHG

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Timepoint	Pre-Dose	◯
	Post-Dose	⬤
Were vital signs assessed?	Yes	◯
	No	⬤

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral	◯
	Axillary	◯
	Other	◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

US3552273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Was the physical examination performed?	Yes ⬤
	No ◯

Date of examination *(dd MMM yyyy)*   28 SEP 2020

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

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   ANXIETY
Participant, Protocol Deviation, or Other, specify

What was the study treatment?   _____

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

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

Treatment Date and Time (derived)   _____

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

What was the frequency of the study treatment dosing?   _____

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

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	28 SEP 2020
Collection time *(00:00-23:59)*	09:30 (24 HR)
Collection date and time (derived)	28 SEP 2020 09:30

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Collection date *(dd MMM yyyy)* | 28 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:32	28 SEP 2020 09:32
Nasopharyngeal Swab 2	No		

US3552273

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ●

                                                                                                    No ○

Continuing Flag   1

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 05 OCT 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 12 OCT 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 19 OCT 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                    No ◯

Continuing Flag   1

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	03 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	03 NOV 2020
Time of assessment *(00:00-23:59)*	14:05 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 14:05
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	99 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552273

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

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.

US3552273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	03 NOV 2020
Collection time *(00:00-23:59)*	14:12 (24 HR)
Collection date and time (derived)	03 NOV 2020 14:12

US3552273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:07**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ⬤

       No ⭘

Continuing Flag   1

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	01 NOV 2020 08:14:43
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	12 NOV 2020 11:40:37
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 07:05:38
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 14:02:18
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	26 NOV 2020 07:19:06
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⬤
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
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 ⬤ Yes ⚪
Date and time of submission	03 DEC 2020 06:23:36
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	10 DEC 2020 07:45:39
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	17 DEC 2020 08:11:36
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	24 DEC 2020 06:59:17
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ●
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ●
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 08:13:01
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	07 JAN 2021 06:40:39
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	14 JAN 2021 07:45:33
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	21 JAN 2021 05:59:10
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	28 JAN 2021 06:27:59
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	04 FEB 2021 08:05:51
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⬤
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⬤
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤
Date and time of submission	12 FEB 2021 06:23:45
Patient Cloud Open Date & Time	11 FEB 2021 00:01

PRODUCTION RELEASE (v12.003 EAB) (1725)

Patient Cloud Close Date & Time   15 FEB 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	18 FEB 2021 06:55:08
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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	27 FEB 2021 21:05:31
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3552273

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:52:44

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		27 FEB 2021 21:05:13

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

| 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 _____

US3552273

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3552273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 DEC 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3552273
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **21 Feb 2021 18:33:43**
Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3552273

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 JAN 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 18:34:06**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3552273

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **27 Feb 2021 17:54:43**

Generated On: 11 Aug 2021 22:52:44

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 25 FEB 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments _____

US3552273

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **27 Feb 2021 17:54:43**

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Yes ●

No ○

Continuing Flag 1

Was this visit performed?   Yes ◯
                                                             No ◯

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3552273
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44

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)	_____

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.

| Was the sample collected? | Yes ◯ |
| | No ◯ |

Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

Is the participant continuing to the next visit?   Yes ◯

                                                                                      No ◯

Continuing Flag

US3552273

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

Form: Visit Date

Data signed: (b) (4) **21 Feb 2021 18:33:43**

Generated On: 11 Aug 2021 22:52:44

| Was this visit performed? | Yes ⬤ |
| | No ◯ |

Visit date (dd MMM yyyy)	17 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

| Folder OID | UNBLND_DECIDE |

US3552273

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

Form: Unblinding

Data signed: (b) (4) **23 Mar 2021 15:33:29**

Generated On: 11 Aug 2021 22:52:44

Date of updated informed consent *(dd MMM yyyy)*	17 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	17 FEB 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ○
	Not Administered ●
Will participant receive mRNA-1273?	Yes ○
	No ●
Placebo Only Flag	1
Continuing with mRNA-1273	

US3552273

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **21 Feb 2021 18:33:43**

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	17 FEB 2021
Collection time *(00:00-23:59)*	15:20 (24 HR)
Collection date and time (derived)	17 FEB 2021 15:20

US3552273

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **21 Feb 2021 18:33:43**

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	17 FEB 2021
Collection time *(00:00 - 23:59)*	15:24
Collection Date and Time (derived)	17 FEB 2021 15:24

US3552273
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **21 Feb 2021 18:33:42**
Generated On: 11 Aug 2021 22:52:44

Did the participant experience any adverse events?   Yes ●

No ◯

If Yes, enter details on the Adverse Events form.

US3552273

Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) 21 Feb 2021 18:33:42
Generated On: 11 Aug 2021 22:52:44

AEID	
Adverse event	WORSENING HYPERTENSION
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	01 SEP 2020
Start time *(00:00-23:59)*	14:07 (24 HR)
AE start date and time (derived)	01 SEP 2020 14:07
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, end date *(dd MMM yyyy)*	
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	

US3552273
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **21 Feb 2021 18:33:42**
Generated On: 11 Aug 2021 22:52:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product
- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ⬤
- Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome
- Fatal ◯
- Not Recovered/Not Resolved ⬤
- Recovered/Resolved ◯
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3552273
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **21 Feb 2021 18:33:42**
Generated On: 11 Aug 2021 22:52:44

AEID	
Adverse event	TACHYCARDIA
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	01 SEP 2020
Start time *(00:00-23:59)*	14:07 (24 HR)
AE start date and time (derived)	01 SEP 2020 14:07
Ongoing?	Yes ●
	No ○
If not Ongoing, end date *(dd MMM yyyy)*	
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
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	None ⬤
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal ◯
	Not Recovered/Not Resolved ⬤
	Recovered/Resolved ◯
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3552273
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **21 Feb 2021 18:33:42**
Generated On: 11 Aug 2021 22:52:44

AEID	
Adverse event	DIARRHEA
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)*	08 FEB 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 FEB 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	

US3552273

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **21 Feb 2021 18:33:42**

Generated On: 11 Aug 2021 22:52:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **21 Feb 2021 18:33:43**

Generated On: 11 Aug 2021 22:52:44

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

No ○

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

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **09 Mar 2021 16:58:14**
Generated On: 11 Aug 2021 22:52:44

Name of Medication	LISINOPRIL/HYDROCHLOROTHI AZIDE
Prophylaxis	Yes ⭘
	No ⬤
Indication	HYPERTENSION
Dose per administration	20 / 25
Dose unit	mg ⬤
	ug ⭘
	mL ⭘
	g ⭘
	IU ⭘
	tablet ⭘
	capsule ⭘
	puff ⭘
	Other ⭘
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ⭘
	three times daily ⭘
	four times daily ⭘
	every other day ⭘
	every week ⭘
	every month ⭘
	as needed ⭘
	once ⭘
	unknown ⭘
	other ⭘
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ⭘
	Subcutaneous ⭘
	Transdermal ⭘

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	UN UNK 1990
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*

Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **09 Mar 2021 16:58:14**

Generated On: 11 Aug 2021 22:52:44

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

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3552273

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **09 Mar 2021 16:58:14**
Generated On: 11 Aug 2021 22:52:44

Name of Medication	ALPRAZOLAM
Prophylaxis	Yes ◯
	No ⬤
Indication	ANXIETY AND TACHYCARDIA AND WORSENING HYPERTENSION
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 ◯

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Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2000
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **09 Mar 2021 16:58:14**
Generated On: 11 Aug 2021 22:52:44

Name of Medication	DOSCOVY
Prophylaxis	Yes ●
	No ○
Indication	HIV PROPHYLAXIS
Dose per administration	200/25
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **09 Mar 2021 16:58:14**

Generated On: 11 Aug 2021 22:52:44

Name of Medication	MULTIVITAMIN

Prophylaxis	Yes ●
	No ○

Indication	HEALTH PROMOTION
Dose per administration	1

Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ●
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○

If frequency is Other, specify	

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN MAR 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **09 Mar 2021 16:58:14**

Generated On: 11 Aug 2021 22:52:44

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ⬤
	No ◯
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	1

Dose unit

- mg ◯
- ug ◯
- mL ◯
- g ◯
- IU ◯
- tablet ◯
- capsule ◯
- puff ◯
- Other ⬤

If dose unit is Other, specify	INJECTION

Frequency

- once daily ◯
- twice daily ◯
- three times daily ◯
- four times daily ◯
- every other day ◯
- every week ◯
- every month ◯
- as needed ◯
- once ⬤
- unknown ◯
- other ◯

If frequency is Other, specify

Route of administration

- Oral ◯
- Topical ◯
- Subcutaneous ◯
- Transdermal ◯
- Intraocular ◯

Intramuscular	●
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	○
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	16 OCT 2020
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **09 Mar 2021 16:58:14**

Generated On: 11 Aug 2021 22:52:44

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

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	14 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **09 Mar 2021 16:58:14**

Generated On: 11 Aug 2021 22:52:44

Name of Medication	MODERNA EUA VACCINE
Prophylaxis	Yes ⬤
	No ◯
Indication	COVID-19 PROPHYLAXIS
Dose per administration	1
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	INJECTION
Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ⬤
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ◯
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **09 Mar 2021 16:58:14**
Generated On: 11 Aug 2021 22:52:44

Intramuscular	●
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	○
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	1 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	1 MAR 2021
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

US3552273
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **21 Feb 2021 18:33:43**
Generated On: 11 Aug 2021 22:52:44

Were any concomitant procedures performed?   Yes ◯

                                                                              No ⬤

If yes, please complete Concomitant Procedures form.

US3552273

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 18:33:43

Generated On: 11 Aug 2021 22:52:44

Date of dosing discontinuation (dd MMM yyyy)	28 SEP 2020
Primary reason for dosing discontinuation	AE (specify) ⬤
	SAE (specify) ◯
	Death ◯
	Lost To Follow-up ◯
	Physician decision (specify) ◯
	Pregnancy ◯
	Protocol deviation (specify) ◯
	Study Terminated By Sponsor ◯
	Withdrawal of consent by participant (specify) ◯
	Due to SARS-COV-2 ◯
	Other ◯
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #1

US3552273
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **23 Mar 2021 15:33:29**
Generated On: 11 Aug 2021 22:52:44

Date of study discontinuation/completion *(dd MMM yyyy)*	01 MAR 2021

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	SUBJECT RECEIVED EUA VACCINE OUTSIDE OF STUDY

If reason for discontinuation is Death, main cause of death	
	Adverse event ◯
	Unknown ◯
	Other ◯

If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	

Was autopsy performed?	
	Yes ◯
	No ◯
	Unknown ◯

Audit

US3552273 (Prod: Saint Louis University)

US3552273

Form: Participant Creation

Generated On: 11 Aug 2021 22:52:44

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:33:44
User entered 'US3552273'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:14:25

US3552273
Form: Participant Creation
Generated On: 11 Aug 2021 22:52:44

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05

US3552273
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:34:07
	(b) (4)	
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	02 Sep 2020 13:26:03
	(b) (4)	

US3552273
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:14:27

US3552273

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:03

US3552273
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'SCRN'	System	02 Sep 2020 13:26:03

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:14:28

US3552273
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:52:44

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '52'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:52:44
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'YEARS'	System	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '52'	System	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Male (M)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:52:44

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '1'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:52:44

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:44

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:44

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:08:27
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:44

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Sep 2020'	System	01 Sep 2020 18:14:53

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2020'	System	01 Sep 2020 18:14:53

US3552273
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:52:44
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	01 Sep 2020 18:14:53

Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:52:44

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:14:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:44

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:44

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:14:27

US3552273

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:44

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:52:44

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:52:44

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:40

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:27:43
Data point term sent to Coder	System	02 Sep 2020 13:27:21
User entered 'hypertension'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un UNK 1990'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Jan 1990'	System	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1990'	System	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:52:44

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:28:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:28:48
Data point term sent to Coder	System	02 Sep 2020 13:28:23
User entered 'gastroesophageal reflux disease'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un UNK 2019'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Jan 2019'	System	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2019'	System	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:52:44

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:10:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:10:39
Data point term sent to Coder	System	20 Oct 2020 14:09:45
Coding entries removed.	Heather Douds (b) (4) (b) (4)	20 Oct 2020 14:09:02
User entered 'General ANXIETY disorder' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	20 Oct 2020 14:09:02
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:56:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:56:44
Data point term sent to Coder	System	02 Sep 2020 13:55:24
User entered 'ANXIETY' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:38
Data point term sent to Coder	System	02 Sep 2020 13:28:26
User entered 'moderate anxiety'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un UNK 2000'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:52:44

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:52:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Jan 2000'	System	02 Sep 2020 13:28:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2000'	System	02 Sep 2020 13:28:03

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:52:44

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:28:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:28:47
Data point term sent to Coder	System	02 Sep 2020 13:28:27
User entered 'sleep apnea'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un Apr 2009'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:52:44

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un Apr 2009'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:52:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Apr 2009'	System	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:52:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2009'	System	02 Sep 2020 13:28:23

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:52:44

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Apr 2009'	System	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:52:44

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2009'	System	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User closed query 'Per DM CLR: Please specify the laterality of RENAL CALCULI (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:49:29
Query 'Per DM CLR: Please specify the laterality of RENAL CALCULI (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' answered with 'Unknown, medical records not available as we are not a clinical site. Con meds within 28 days of 1st vaccination are recorded as per protocol. ' (Site from DM).	Heather Douds (b) (4) (b) (4)	06 Oct 2020 14:46:19
User opened query 'Per DM CLR: Please specify the laterality of RENAL CALCULI (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:51:14
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Renal calculi - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:29:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:29:49
Data point term sent to Coder	System	02 Sep 2020 13:29:29
User entered 'renal calculi'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un UNK 2003'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:52:44

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un UNK 2003'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:52:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Jan 2003'	System	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:52:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2003'	System	02 Sep 2020 13:29:07

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Jan 2003'	System	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:52:44

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2003'	System	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:56:27
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Con meds within 28 days of 1st vaccination are recorded as per protocol. ' (Site from DM).	Heather Douds (b) (4) (b) (4)	06 Oct 2020 14:46:40
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:06:33
Data hard unlocked.		06 Oct 2020 03:06:25
Data hard locked.		06 Oct 2020 03:06:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Bronchitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:56:45
Data point term sent to Coder	System	02 Sep 2020 13:55:27
User entered 'BRONCHITIS' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:55:26
Data point term sent to Coder	System	02 Sep 2020 13:31:34
User entered 'upper respiratory or infections bronchitis'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un UNK 2000'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Jan 2000'	System	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2000'	System	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:52:44

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Lithotripsy, LLT: Lithotripsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:32:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:32:54
Data point term sent to Coder	System	02 Sep 2020 17:31:57
User entered 'lithotripsy'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un UNK 2003'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:52:44

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'un UNK 2003'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

FDA-CBER-2022-1614-2713333

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:52:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:52:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Jan 2003'	System	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:52:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2003'	System	02 Sep 2020 17:31:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'Jan 2003'	System	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:52:44

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '2003'	System	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:08:40
User entered '1 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '12:00'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '01 Sep 2020 12:00'	System	10 Nov 2020 20:08:40
User entered '1 Sep 2020 12:00'	System	02 Sep 2020 13:31:35

US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '69' in	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35
DataPoint set to visible.	System	01 Sep 2020 18:15:05

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '185.6' lb	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35
DataPoint set to visible.	System	01 Sep 2020 18:15:05

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US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '27.46564'	System	02 Sep 2020 13:31:35
DataPoint set to visible.	System	01 Sep 2020 18:15:05

US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'kg/m2'	System	02 Sep 2020 13:31:35
DataPoint set to visible.	System	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'bpm'	System	02 Sep 2020 13:31:35

US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'breaths/min'	System	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	02 Sep 2020 13:31:35

US3552273
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	02 Sep 2020 13:31:35

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01

US3552273

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:11:50
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:46

US3552273

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:44

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:11:50
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:46

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:52:44
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:52:44
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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'flew 6 weeks ago and goes to the (b) (6) (b) (6) to see staff with mask twice a month for 2 days, work primarily from home, grocery shopping once a week, one on one person trainer in public gym'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:52:44
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '1'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:52:44
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:13

US3552273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:12:01
User entered '1 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:13

US3552273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:13

US3552273
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'VISIT1'	System	02 Sep 2020 13:35:13

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:14:32

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:44

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '110608'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:14:32

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:44

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:14:32

US3552273

Folder: Visit 1 Day 1

Form: Randomization

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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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

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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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:44

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:44

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	21 Sep 2020 17:45:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:59:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:59:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:52:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:52:44
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:12:16
User entered '1 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '12:00'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '01 Sep 2020 12:00'	System	10 Nov 2020 20:12:16
User entered '1 Sep 2020 12:00'	System	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '97.2' F	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '80'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'bpm'	System	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '24'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'breaths/min'	System	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '146'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '77'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	02 Sep 2020 13:39:50

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:52:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:12:16
User entered '1 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '14:07'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '01 Sep 2020 14:07'	System	10 Nov 2020 20:12:16
User entered '1 Sep 2020 14:07'	System	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '97.9' F	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '124'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'bpm'	System	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '22'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'breaths/min'	System	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 18:17:07
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Clinically significant, AE entered' (Site from System).	Heather Douds (b) (4) (b) (4)	03 Sep 2020 14:57:59
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 13:40:27
User entered '177'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 18:17:15
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Clinically significant, AE entered' (Site from System).	Heather Douds (b) (4) (b) (4)	03 Sep 2020 14:57:57
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 13:40:27
User entered '105'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:02

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:44

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:42:39

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:52:44
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:42:39

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:34:07
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:42:39

FDA-CBER-2022-1614-2713438

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 18:42:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:12:28
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:42:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '13:37'	(b) (4), (b) (6)	01 Sep 2020 18:42:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '01 Sep 2020 13:37'	System	10 Nov 2020 20:12:28
User entered '1 Sep 2020 13:37'	System	01 Sep 2020 18:42:39

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Folder: Visit 1 Day 1

Form: Exposure

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Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Sep 2020 18:42:39

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'ONCE'	System	01 Sep 2020 18:42:39

US3552273
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:52:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:15

US3552273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:12:35
User entered '1 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:15

US3552273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '13:00'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:15

US3552273
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:52:44
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '01 Sep 2020 13:00'	System	10 Nov 2020 20:12:35
User entered '1 Sep 2020 13:00'	System	02 Sep 2020 13:42:15

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:52:44

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:12:42
User entered '1 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:44

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '13:12'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '01 Sep 2020 13:12'	System	10 Nov 2020 20:12:42
User entered '1 Sep 2020 13:12'	System	02 Sep 2020 13:42:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:52:44
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:30:46

US3552273

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	08 Sep 2020 17:30:46

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:14:31', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9e144a6c-7d0d-4a80-b086-a2bc92d1a199'	System	01 Sep 2020 21:15:08
User entered 'Yes (Y)'	System	01 Sep 2020 21:15:08

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:14:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9e144a6c-7d0d-4a80-b086-a2bc92d1a199'	System	01 Sep 2020 21:15:08
User entered '98.3'	System	01 Sep 2020 21:15:08

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:15:02', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9e144a6c-7d0d-4a80-b086-a2bc92d1a199'	System	01 Sep 2020 21:15:08
User entered 'No (N)'	System	01 Sep 2020 21:15:08

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:15:05', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9e144a6c-7d0d-4a80-b086-a2bc92d1a199'	System	01 Sep 2020 21:15:08
User entered '01 Sep 2020 16:15'	System	01 Sep 2020 21:15:08

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 13:57'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 16:27'	System	01 Sep 2020 18:42:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:55:42', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a0aaf5e0-b661-4e04-add7-9dc935f588e4'	System	02 Sep 2020 15:56:05
User entered 'Yes (Y)'	System	02 Sep 2020 15:56:05

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:55:53', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a0aaf5e0-b661-4e04-add7-9dc935f588e4'	System	02 Sep 2020 15:56:05
User entered '97.8'	System	02 Sep 2020 15:56:05

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:55:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a0aaf5e0-b661-4e04-add7-9dc935f588e4'	System	02 Sep 2020 15:56:05
User entered 'No (N)'	System	02 Sep 2020 15:56:05

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:01', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a0aaf5e0-b661-4e04-add7-9dc935f588e4'	System	02 Sep 2020 15:56:05
User entered '02 Sep 2020 10:56'	System	02 Sep 2020 15:56:05

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 17:22'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 2'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'd4eb0921-73d7-420e-9db8-a58ccd11d6f2'	System	03 Sep 2020 03:06:04
User entered 'Yes (Y)'	System	03 Sep 2020 03:06:04

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:55', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'd4eb0921-73d7-420e-9db8-a58ccd11d6f2'	System	03 Sep 2020 03:06:04
User entered '98.0'	System	03 Sep 2020 03:06:04

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'd4eb0921-73d7-420e-9db8-a58ccd11d6f2'	System	03 Sep 2020 03:06:04
User entered 'No (N)'	System	03 Sep 2020 03:06:04

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:06:01', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'd4eb0921-73d7-420e-9db8-a58ccd11d6f2'	System	03 Sep 2020 03:06:04
User entered '02 Sep 2020 22:06'	System	03 Sep 2020 03:06:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 3'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T21:28:07', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '4e787de5-b7f1-4824-9997-77e688290534'	System	04 Sep 2020 02:30:28
User entered 'Yes (Y)'	System	04 Sep 2020 02:30:28

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:52:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T21:30:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '4e787de5-b7f1-4824-9997-77e688290534'	System	04 Sep 2020 02:30:28
User entered '96.0'	System	04 Sep 2020 02:30:28

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T21:30:22', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '4e787de5-b7f1-4824-9997-77e688290534'	System	04 Sep 2020 02:30:28
User entered 'No (N)'	System	04 Sep 2020 02:30:28

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T21:30:25', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '4e787de5-b7f1-4824-9997-77e688290534'	System	04 Sep 2020 02:30:28
User entered '03 Sep 2020 21:30'	System	04 Sep 2020 02:30:28

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 4'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:13', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1bbca0fa-d8e0-44cb-ad93-e767fa0eb3f4'	System	04 Sep 2020 22:16:37
User entered 'Yes (Y)'	System	04 Sep 2020 22:16:37

FDA-CBER-2022-1614-2713490

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:28', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1bbca0fa-d8e0-44cb-ad93-e767fa0eb3f4'	System	04 Sep 2020 22:16:37
User entered '98.4'	System	04 Sep 2020 22:16:37

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1bbca0fa-d8e0-44cb-ad93-e767fa0eb3f4'	System	04 Sep 2020 22:16:37
User entered 'No (N)'	System	04 Sep 2020 22:16:37

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1bbca0fa-d8e0-44cb-ad93-e767fa0eb3f4'	System	04 Sep 2020 22:16:37
User entered '04 Sep 2020 17:16'	System	04 Sep 2020 22:16:37

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 5'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T21:42:15', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '84c5e8eb-cf2b-43bc-a6c0-bd3eb0b27624'	System	06 Sep 2020 02:42:26
User entered 'Yes (Y)'	System	06 Sep 2020 02:42:26

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T21:42:19', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '84c5e8eb-cf2b-43bc-a6c0-bd3eb0b27624'	System	06 Sep 2020 02:42:26
User entered '97.1'	System	06 Sep 2020 02:42:26

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T21:42:22', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '84c5e8eb-cf2b-43bc-a6c0-bd3eb0b27624'	System	06 Sep 2020 02:42:26
User entered 'No (N)'	System	06 Sep 2020 02:42:26

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T21:42:24', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '84c5e8eb-cf2b-43bc-a6c0-bd3eb0b27624'	System	06 Sep 2020 02:42:26
User entered '05 Sep 2020 21:42'	System	06 Sep 2020 02:42:26

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 6'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:51:42', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3b4619fb-6436-4046-82ce-b1c7ee2a685f'	System	06 Sep 2020 23:52:00
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:00

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:51:53', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3b4619fb-6436-4046-82ce-b1c7ee2a685f'	System	06 Sep 2020 23:52:00
User entered '97.8'	System	06 Sep 2020 23:52:00

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:51:56', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3b4619fb-6436-4046-82ce-b1c7ee2a685f'	System	06 Sep 2020 23:52:00
User entered 'No (N)'	System	06 Sep 2020 23:52:00

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:51:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3b4619fb-6436-4046-82ce-b1c7ee2a685f'	System	06 Sep 2020 23:52:00
User entered '06 Sep 2020 18:51'	System	06 Sep 2020 23:52:00

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:52:44
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 7'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T21:24:54', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c38bb5c6-06b4-4d4f-bc21-84b7fb156a3f'	System	08 Sep 2020 02:25:09
User entered 'Yes (Y)'	System	08 Sep 2020 02:25:09

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T21:24:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c38bb5c6-06b4-4d4f-bc21-84b7fb156a3f'	System	08 Sep 2020 02:25:09
User entered '98.0'	System	08 Sep 2020 02:25:09

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T21:25:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c38bb5c6-06b4-4d4f-bc21-84b7fb156a3f'	System	08 Sep 2020 02:25:09
User entered 'No (N)'	System	08 Sep 2020 02:25:09

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:44

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T21:25:05', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c38bb5c6-06b4-4d4f-bc21-84b7fb156a3f'	System	08 Sep 2020 02:25:09
User entered '07 Sep 2020 21:25'	System	08 Sep 2020 02:25:09

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:52:44
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered 'None (1)'	System	01 Sep 2020 21:13:57

FDA-CBER-2022-1614-2713518

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:43', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered 'No (N)'	System	01 Sep 2020 21:13:57

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:46', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered 'No (N)'	System	01 Sep 2020 21:13:57

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:50', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered 'None (1)'	System	01 Sep 2020 21:13:57

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:53', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered '01 Sep 2020 16:13'	System	01 Sep 2020 21:13:57

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:52:44
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 13:57'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 16:27'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:11', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered 'None (1)'	System	02 Sep 2020 15:58:08

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:15', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered 'No (N)'	System	02 Sep 2020 15:58:08

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:17', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered 'No (N)'	System	02 Sep 2020 15:58:08

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:20', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered 'None (1)'	System	02 Sep 2020 15:58:08

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:22', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered '02 Sep 2020 10:56'	System	02 Sep 2020 15:58:08

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:52:44
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 17:22'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 2'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:17', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered 'None (1)'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:19', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered 'No (N)'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:21', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered 'No (N)'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:28', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered 'None (1)'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:44

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered '02 Sep 2020 22:05'	System	03 Sep 2020 03:05:33

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:52:44
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 3'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:13', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered 'None (1)'	System	03 Sep 2020 23:59:24

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:15', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered 'No (N)'	System	03 Sep 2020 23:59:24

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered 'No (N)'	System	03 Sep 2020 23:59:24

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:21', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered 'None (1)'	System	03 Sep 2020 23:59:24

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:23', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered '03 Sep 2020 18:59'	System	03 Sep 2020 23:59:24

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:52:44
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 4'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered 'None (1)'	System	04 Sep 2020 22:16:50

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:41', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered 'No (N)'	System	04 Sep 2020 22:16:50

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:43', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered 'No (N)'	System	04 Sep 2020 22:16:50

FDA-CBER-2022-1614-2713552

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:45', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered 'None (1)'	System	04 Sep 2020 22:16:50

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:44

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:47', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered '04 Sep 2020 17:16'	System	04 Sep 2020 22:16:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 5'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:22', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered 'None (1)'	System	05 Sep 2020 22:02:36

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:24', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered 'No (N)'	System	05 Sep 2020 22:02:36

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:25', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered 'No (N)'	System	05 Sep 2020 22:02:36

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:28', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered 'None (1)'	System	05 Sep 2020 22:02:36

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:52:44
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered '05 Sep 2020 17:02'	System	05 Sep 2020 22:02:36

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:52:44
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 6'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:42', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered 'None (1)'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:44', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered 'No (N)'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:45', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered 'No (N)'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:48', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered 'None (1)'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:44

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:50', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered '06 Sep 2020 18:38'	System	06 Sep 2020 23:38:53

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:52:44
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 7'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered 'None (1)'	System	07 Sep 2020 22:19:41

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered 'No (N)'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered 'No (N)'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered 'None (1)'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:44

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered '07 Sep 2020 17:19'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:52:44
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:05', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:52:44
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:12', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:52:44
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:14', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:52:44
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:16', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:27', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'No (N)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered '01 Sep 2020 16:13'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 13:57'	System	01 Sep 2020 18:42:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 16:27'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'No interference with activity (1)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:52:44
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:40', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:43', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'No (N)'	System	02 Sep 2020 15:06:50

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:52:44
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:46', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered '02 Sep 2020 10:06'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '01 Sep 2020 17:22'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 2'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:52:44
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:04:54', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'No interference with activity (1)'	System	03 Sep 2020 03:05:18

FDA-CBER-2022-1614-2713604

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:52:44
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:04:56', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:52:44
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:04:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:04:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:01', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:52:44
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'No (N)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:44

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:13', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered '02 Sep 2020 22:05'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 3'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:58:55', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:58:56', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:58:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:00', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:02', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:52:44
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:06', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'No (N)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:09', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered '03 Sep 2020 18:59'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 4'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:41', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:48', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:50', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:52', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:54', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:55', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:57', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'No (N)'	System	04 Sep 2020 22:16:03

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:52:44
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered '04 Sep 2020 17:15'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 5'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:52:44
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:05', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:07', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:09', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:52:44
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:11', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:52:44
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:12', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:14', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'No (N)'	System	05 Sep 2020 22:02:19

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:52:44
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:17', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered '05 Sep 2020 17:02'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 6'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:29', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:31', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:34', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'No (N)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered '06 Sep 2020 18:38'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 7'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'No interference with activity (1)'	System	07 Sep 2020 22:19:28

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:52:44
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:12', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:15', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:16', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:52:44
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:19', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:24', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'No (N)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:44

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:26', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered '07 Sep 2020 17:19'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	07 Sep 2020 22:19:28
User entered 'Day 8'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-08T15:50:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1dcfb5fb-333e-48e8-96e6-318a37349d7d'	System	08 Sep 2020 20:50:09
User entered 'None (0)'	System	08 Sep 2020 20:50:09

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:52:44

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-08T15:50:06', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1dcfb5fb-333e-48e8-96e6-318a37349d7d'	System	08 Sep 2020 20:50:09
User entered '08 Sep 2020 15:50'	System	08 Sep 2020 20:50:09

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 22:19:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	07 Sep 2020 22:19:28
User entered 'Day 8'	System	07 Sep 2020 22:19:28

FDA-CBER-2022-1614-2713674

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-08T15:50:11', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '91c5725a-cd13-4b9f-9605-eb3bb167d4d7'	System	08 Sep 2020 20:50:15
User entered 'No (N)'	System	08 Sep 2020 20:50:15

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:52:44

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-08T15:50:14', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '91c5725a-cd13-4b9f-9605-eb3bb167d4d7'	System	08 Sep 2020 20:50:15
User entered '08 Sep 2020 15:50'	System	08 Sep 2020 20:50:15

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:52:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:52:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 22:19:28

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:31:32

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '08 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:12:51
User entered '8 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:31:32

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:31:32

US3552273
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:31:32

US3552273

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	15 Sep 2020 17:44:32

US3552273
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	15 Sep 2020 17:44:32

US3552273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	15 Sep 2020 17:44:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '15 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	15 Sep 2020 17:44:40

US3552273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	15 Sep 2020 17:44:40

US3552273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	15 Sep 2020 17:44:40

US3552273

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:44:56

US3552273
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	23 Sep 2020 14:44:56

US3552273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:45:07

US3552273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '22 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:45:07

US3552273
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:45:07

US3552273
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:45:07

US3552273
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:29:12

US3552273
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	28 Sep 2020 16:29:12

US3552273
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:29:24

US3552273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:29:24

US3552273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:29:24

US3552273
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'VISIT2'	System	28 Sep 2020 16:29:24

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '09:02'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '28 Sep 2020 09:02'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '98.1' F	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:52:44
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:20:40
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS, AE ongoing' (Site from System).	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:12:57
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 16:31:02
User entered '140'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:52:44
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'bpm'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '18'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'breaths/min'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '162'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '98'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:34:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:44

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:34:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User closed query 'Per CDM: Please complete the end of study dosing discontinuation page.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:39:09
Query 'Per CDM: Please complete the end of study dosing discontinuation page.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	06 Oct 2020 14:05:22
User opened query 'Per CDM: Please complete the end of study dosing discontinuation page.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:58:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Physician Decision (PHYSICIAN DECISION)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Anxiety' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:19:38
User entered 'BP and HP elevated due to anxiety per Dr. Frey'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:35:51

FDA-CBER-2022-1614-2713741

US3552273
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:52:44

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:13

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:13

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '09:30'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:13

US3552273
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:52:44
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '28 Sep 2020 09:30'	System	28 Sep 2020 16:36:13

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:52:44

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:44

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '09:32'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '28 Sep 2020 09:32'	System	28 Sep 2020 16:36:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered empty.	System	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 18:30:39

US3552273
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	05 Oct 2020 18:30:39

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 18:30:47

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '05 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:13:09
User entered '5 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 18:30:47

US3552273
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 18:30:47

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 18:30:47

US3552273

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:53:55

US3552273
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	12 Oct 2020 18:53:55

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:54:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '12 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:54:04

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:54:04

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:54:04

US3552273

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:49:29

US3552273
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	19 Oct 2020 17:49:29

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:49:37

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '19 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:49:37

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:49:37

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:49:37

US3552273
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:02:54

US3552273
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	04 Nov 2020 13:02:54

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:03

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '03 Nov 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:13:17
User entered '3 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:03

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:03

Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'VISIT3'	System	04 Nov 2020 13:03:03

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '03 Nov 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:13:24
User entered '3 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '14:05'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '03 Nov 2020 14:05'	System	10 Nov 2020 20:13:24
User entered '3 Nov 2020 14:05'	System	04 Nov 2020 13:03:32

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '97.5' F	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '99'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'bpm'	System	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '16'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'breaths/min'	System	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '122'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:44

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '80'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered 'mmHg'	System	04 Nov 2020 13:03:32

FDA-CBER-2022-1614-2713796

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01

US3552273
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:52:44
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01

US3552273

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:40

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:40

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:51

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '03 Nov 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:13:33
User entered '3 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '14:12'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:51

US3552273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '03 Nov 2020 14:12'	System	10 Nov 2020 20:13:33
User entered '3 Nov 2020 14:12'	System	04 Nov 2020 13:03:51

US3552273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	24 Nov 2020 13:39:51

US3552273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	24 Nov 2020 13:39:51

US3552273
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 64'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-11-01T08:14:36', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'e6a1c880-5e3b-4a3b-9d3f-6c7eb7bdabea'	System	01 Nov 2020 16:14:47
User entered 'No (N)'	System	01 Nov 2020 16:14:47

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-11-01T08:14:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'e6a1c880-5e3b-4a3b-9d3f-6c7eb7bdabea'	System	01 Nov 2020 16:14:47
User entered 'No (N)'	System	01 Nov 2020 16:14:47

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-11-01T08:14:43', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'e6a1c880-5e3b-4a3b-9d3f-6c7eb7bdabea'	System	01 Nov 2020 16:14:47
User entered '01 Nov 2020 08:14:43'	System	01 Nov 2020 16:14:47

US3552273
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 71'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-12T11:40:27', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '18819f54-e2ad-44f0-a8f7-c0933f73fe35'	System	12 Nov 2020 17:40:40
User entered 'No (N)'	System	12 Nov 2020 17:40:40

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-12T11:40:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '18819f54-e2ad-44f0-a8f7-c0933f73fe35'	System	12 Nov 2020 17:40:40
User entered 'No (N)'	System	12 Nov 2020 17:40:40

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-12T11:40:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '18819f54-e2ad-44f0-a8f7-c0933f73fe35'	System	12 Nov 2020 17:40:40
User entered '12 Nov 2020 11:40:37'	System	12 Nov 2020 17:40:40

US3552273
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 18:42:39

US3552273
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 78'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-15T07:05:26', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3d72322e-db56-4ef6-8880-d03faff13eeb'	System	15 Nov 2020 13:05:41
User entered 'No (N)'	System	15 Nov 2020 13:05:41

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-15T07:05:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3d72322e-db56-4ef6-8880-d03faff13eeb'	System	15 Nov 2020 13:05:41
User entered 'No (N)'	System	15 Nov 2020 13:05:41

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-15T07:05:38', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3d72322e-db56-4ef6-8880-d03faff13eeb'	System	15 Nov 2020 13:05:41
User entered '15 Nov 2020 07:05:38'	System	15 Nov 2020 13:05:41

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:12:27
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 18:42:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-22T14:02:02', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'f97fc241-6189-4432-a1f7-b56e124b641c'	System	22 Nov 2020 20:02:22
User entered 'No (N)'	System	22 Nov 2020 20:02:22

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-22T14:02:06', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'f97fc241-6189-4432-a1f7-b56e124b641c'	System	22 Nov 2020 20:02:22
User entered 'No (N)'	System	22 Nov 2020 20:02:22

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-22T14:02:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'f97fc241-6189-4432-a1f7-b56e124b641c'	System	22 Nov 2020 20:02:22
User entered '22 Nov 2020 14:02:18'	System	22 Nov 2020 20:02:22

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-26T07:18:55', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '74ef8285-60a3-4fc8-9dbb-58eb023d7266'	System	26 Nov 2020 13:19:09
User entered 'No (N)'	System	26 Nov 2020 13:19:09

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-26T07:19:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '74ef8285-60a3-4fc8-9dbb-58eb023d7266'	System	26 Nov 2020 13:19:09
User entered 'No (N)'	System	26 Nov 2020 13:19:09

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-26T07:19:06', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '74ef8285-60a3-4fc8-9dbb-58eb023d7266'	System	26 Nov 2020 13:19:09
User entered '26 Nov 2020 07:19:06'	System	26 Nov 2020 13:19:09

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:54:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-03T06:23:02', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3d742e4-2413-4136-b720-c2157eeb2139'	System	03 Dec 2020 12:23:40
User entered 'Yes (Y)'	System	03 Dec 2020 12:23:40

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-03T06:23:07', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3d742e4-2413-4136-b720-c2157eeb2139'	System	03 Dec 2020 12:23:40
User entered 'No (N)'	System	03 Dec 2020 12:23:40

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-03T06:23:17', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3d742e4-2413-4136-b720-c2157eeb2139'	System	03 Dec 2020 12:23:40
User entered 'No (N)'	System	03 Dec 2020 12:23:40

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-03T06:23:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3d742e4-2413-4136-b720-c2157eeb2139'	System	03 Dec 2020 12:23:40
User entered 'No (N)'	System	03 Dec 2020 12:23:40

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-03T06:23:36', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3d742e4-2413-4136-b720-c2157eeb2139'	System	03 Dec 2020 12:23:40
User entered '03 Dec 2020 06:23:36'	System	03 Dec 2020 12:23:40

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:54:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-10T07:45:28', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '09296cab-b673-4859-a7a7-a22f9a6f1acd'	System	10 Dec 2020 13:45:42
User entered 'No (N)'	System	10 Dec 2020 13:45:42

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-10T07:45:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '09296cab-b673-4859-a7a7-a22f9a6f1acd'	System	10 Dec 2020 13:45:42
User entered 'No (N)'	System	10 Dec 2020 13:45:42

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-10T07:45:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '09296cab-b673-4859-a7a7-a22f9a6f1acd'	System	10 Dec 2020 13:45:42
User entered '10 Dec 2020 07:45:39'	System	10 Dec 2020 13:45:42

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-17T08:11:25', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c7b73834-281a-4980-93cc-54ab8beecf08'	System	17 Dec 2020 14:11:39
User entered 'No (N)'	System	17 Dec 2020 14:11:39

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-17T08:11:34', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c7b73834-281a-4980-93cc-54ab8beecf08'	System	17 Dec 2020 14:11:39
User entered 'No (N)'	System	17 Dec 2020 14:11:39

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-17T08:11:36', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c7b73834-281a-4980-93cc-54ab8beecf08'	System	17 Dec 2020 14:11:39
User entered '17 Dec 2020 08:11:36'	System	17 Dec 2020 14:11:39

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-24T06:59:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '30969c3e-b222-472c-b7fb-e884cfa70dd0'	System	24 Dec 2020 12:59:21
User entered 'No (N)'	System	24 Dec 2020 12:59:21

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-24T06:59:14', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '30969c3e-b222-472c-b7fb-e884cfa70dd0'	System	24 Dec 2020 12:59:21
User entered 'No (N)'	System	24 Dec 2020 12:59:21

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-24T06:59:17', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '30969c3e-b222-472c-b7fb-e884cfa70dd0'	System	24 Dec 2020 12:59:21
User entered '24 Dec 2020 06:59:17'	System	24 Dec 2020 12:59:21

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-31T08:12:45', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7d366f35-8a7d-407e-8de8-e931eda3d218'	System	31 Dec 2020 14:13:12
User entered 'No (N)'	System	31 Dec 2020 14:13:12

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-31T08:12:50', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7d366f35-8a7d-407e-8de8-e931eda3d218'	System	31 Dec 2020 14:13:12
User entered 'Yes (Y)'	System	31 Dec 2020 14:13:12

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-31T08:12:54', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7d366f35-8a7d-407e-8de8-e931eda3d218'	System	31 Dec 2020 14:13:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Dec 2020 14:13:12

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-12-31T08:13:01', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7d366f35-8a7d-407e-8de8-e931eda3d218'	System	31 Dec 2020 14:13:12
User entered '31 Dec 2020 08:13:01'	System	31 Dec 2020 14:13:12

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-07T06:40:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '735a9871-0c6a-4dc3-a189-698c4ebbfdb1'	System	07 Jan 2021 12:40:41
User entered 'No (N)'	System	07 Jan 2021 12:40:41

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-07T06:40:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '735a9871-0c6a-4dc3-a189-698c4ebbfdb1'	System	07 Jan 2021 12:40:41
User entered 'No (N)'	System	07 Jan 2021 12:40:41

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-07T06:40:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '735a9871-0c6a-4dc3-a189-698c4ebbfdb1'	System	07 Jan 2021 12:40:41
User entered '07 Jan 2021 06:40:39'	System	07 Jan 2021 12:40:41

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-14T07:45:23', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '82a9a788-ad66-46c2-b9a8-19039e600a4b'	System	14 Jan 2021 13:45:38
User entered 'No (N)'	System	14 Jan 2021 13:45:38

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-14T07:45:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '82a9a788-ad66-46c2-b9a8-19039e600a4b'	System	14 Jan 2021 13:45:38
User entered 'No (N)'	System	14 Jan 2021 13:45:38

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-14T07:45:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '82a9a788-ad66-46c2-b9a8-19039e600a4b'	System	14 Jan 2021 13:45:38
User entered '14 Jan 2021 07:45:33'	System	14 Jan 2021 13:45:38

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-21T05:58:57', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '571c1099-6042-43fe-b6b4-f63c3c26670c'	System	21 Jan 2021 11:59:12
User entered 'No (N)'	System	21 Jan 2021 11:59:12

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-21T05:59:06', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '571c1099-6042-43fe-b6b4-f63c3c26670c'	System	21 Jan 2021 11:59:12
User entered 'No (N)'	System	21 Jan 2021 11:59:12

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-21T05:59:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '571c1099-6042-43fe-b6b4-f63c3c26670c'	System	21 Jan 2021 11:59:12
User entered '21 Jan 2021 05:59:10'	System	21 Jan 2021 11:59:12

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-28T06:27:51', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '320d2f37-1368-44c3-abb5-ae1b6eb6ff64'	System	28 Jan 2021 11:28:02
User entered 'No (N)'	System	28 Jan 2021 11:28:02

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-28T06:27:55', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '320d2f37-1368-44c3-abb5-ae1b6eb6ff64'	System	28 Jan 2021 11:28:02
User entered 'No (N)'	System	28 Jan 2021 11:28:02

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-01-28T06:27:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '320d2f37-1368-44c3-abb5-ae1b6eb6ff64'	System	28 Jan 2021 11:28:02
User entered '28 Jan 2021 06:27:59'	System	28 Jan 2021 11:28:02

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-04T08:05:45', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '78d5180f-3a45-4ea6-ae5a-f5eeda3bdf16'	System	04 Feb 2021 13:05:52
User entered 'No (N)'	System	04 Feb 2021 13:05:52

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-04T08:05:48', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '78d5180f-3a45-4ea6-ae5a-f5eeda3bdf16'	System	04 Feb 2021 13:05:52
User entered 'No (N)'	System	04 Feb 2021 13:05:52

US3552273

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-04T08:05:51', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '78d5180f-3a45-4ea6-ae5a-f5eeda3bdf16'	System	04 Feb 2021 13:05:52
User entered '04 Feb 2021 08:05:51'	System	04 Feb 2021 13:05:52

US3552273

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:52:44

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:22:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered 'Yes (Y)'	System	12 Feb 2021 12:23:54

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:22:34', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered 'No (N)'	System	12 Feb 2021 12:23:54

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:22:49', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered 'Yes (Y)'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '1'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '1'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '1'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '0'	System	12 Feb 2021 12:23:54

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '1'	System	12 Feb 2021 12:23:54

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:27', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Feb 2021 12:23:54

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered 'Yes (Y)'	System	12 Feb 2021 12:23:54

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-12T06:23:45', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'b303bd00-841e-409b-851d-fd1c08bb5b93'	System	12 Feb 2021 12:23:54
User entered '12 Feb 2021 06:23:45'	System	12 Feb 2021 12:23:54

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-18T06:54:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'bb8a5a73-804b-4087-a347-a75519c9e56e'	System	18 Feb 2021 12:55:10
User entered 'No (N)'	System	18 Feb 2021 12:55:10

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-18T06:55:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'bb8a5a73-804b-4087-a347-a75519c9e56e'	System	18 Feb 2021 12:55:10
User entered 'No (N)'	System	18 Feb 2021 12:55:10

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-18T06:55:08', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'bb8a5a73-804b-4087-a347-a75519c9e56e'	System	18 Feb 2021 12:55:10
User entered '18 Feb 2021 06:55:08'	System	18 Feb 2021 12:55:10

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-27T15:05:22-06:00', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1714c3df-3e91-4777-b6c6-56fc94fa4210'	System	27 Feb 2021 21:05:35
User entered 'No (N)'	System	27 Feb 2021 21:05:35

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Have you been exposed to someone with 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 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-27T15:05:27-06:00', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1714c3df-3e91-4777-b6c6-56fc94fa4210'	System	27 Feb 2021 21:05:35
User entered 'No (N)'	System	27 Feb 2021 21:05:35

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-27T15:05:31-06:00', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1714c3df-3e91-4777-b6c6-56fc94fa4210'	System	27 Feb 2021 21:05:35
User entered '27 Feb 2021 21:05:31'	System	27 Feb 2021 21:05:35

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:44

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:52:44
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:52:44

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)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-27T15:05:10-06:00', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '722503fe-5c97-4f1e-9262-81b9c80666d5'	System	27 Feb 2021 21:05:19
User entered 'No (N)'	System	27 Feb 2021 21:05:19

US3552273

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:52:44

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2021-02-27T15:05:13-06:00', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '722503fe-5c97-4f1e-9262-81b9c80666d5'	System	27 Feb 2021 21:05:19
User entered '27 Feb 2021 21:05:13'	System	27 Feb 2021 21:05:19

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	24 Nov 2020 13:40:23

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '23 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	24 Nov 2020 13:40:23

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	24 Nov 2020 13:40:23

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	24 Nov 2020 13:40:23

US3552273

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Dec 2020 19:43:31

US3552273
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	29 Dec 2020 19:43:31

US3552273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Dec 2020 19:43:43

US3552273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '29 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	29 Dec 2020 19:43:43

US3552273
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	29 Dec 2020 19:43:43

US3552273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Dec 2020 19:43:43

US3552273

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Jan 2021 15:11:21

US3552273
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	27 Jan 2021 15:11:21

US3552273

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Jan 2021 15:11:30

US3552273
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered '26 Jan 2021'	Stanley Doublin (b) (4) (b) (4)	27 Jan 2021 15:11:30

US3552273
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	27 Jan 2021 15:11:30

US3552273

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Jan 2021 15:11:30

US3552273

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:34:07
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Feb 2021 15:32:18

US3552273
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	18 Feb 2021 15:32:18

US3552273
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:43
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:14:18

US3552273
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:43
User entered '25 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:14:18

US3552273

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:44

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:43
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:14:18

US3552273
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:52:44
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:43
User entered empty.	Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:14:18

US3552273

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:44

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:43
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	26 Feb 2021 16:15:32

US3552273
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:52:44
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:14:01
User entered '1'	System	26 Feb 2021 16:15:32

US3552273

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

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:42:38

FDA-CBER-2022-1614-2713965

US3552273

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

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '17 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:42:38

US3552273

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

Form: Visit Date

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:42:38

US3552273
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:52:44
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered 'UNBLND_DECIDE'	System	18 Feb 2021 14:42:38

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '17 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:29

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:33:29
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:16:01

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:29

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:33:29
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:16:01

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '17 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:29

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Placebo (Placebo)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:29

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Placebo (Placebo)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:29

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Administered (NA)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:29

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:29

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	18 Feb 2021 14:43:29

US3552273

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

Form: Unblinding

Generated On: 11 Aug 2021 22:52:44

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	18 Feb 2021 14:43:29

US3552273

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:45

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '17 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:45

US3552273

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '15:20'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:45

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '17 Feb 2021 15:20'	System	18 Feb 2021 14:43:45

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:52:44

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:55

US3552273

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:52:44

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '17 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:55

US3552273

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '15:24'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:43:55

US3552273

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:52:44

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '17 Feb 2021 15:24'	System	18 Feb 2021 14:43:55

FDA-CBER-2022-1614-2713987

US3552273

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:52:44

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User closed query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for CHILLS, FATIGUE, and HEADACHE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).		24 Mar 2021 12:43:32
Query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for CHILLS, FATIGUE, and HEADACHE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' answered with 'subject did not report these symptoms to site. recorded what was reported. ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	23 Mar 2021 14:42:03
User opened query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for CHILLS, FATIGUE, and HEADACHE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 02:05:52
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:05:06

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:52:44

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:52:44

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:33:44
User closed query 'Per DM CLR: RQ: Response noted, however, the term was reverted to "HYPERTENSTION" only. Please review and verify if this is a worsening of the Med History condition. If yes, please add "WORSENING" in the AE term. If not, kindly remove this entry. Otherwise, clarify in query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:26:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:00:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:00:36
Data point term sent to Coder	System	23 Oct 2020 14:59:39
Query 'Per DM CLR: RQ: Response noted, however, the term was reverted to "HYPERTENSTION" only. Please review and verify if this is a worsening of the Med History condition. If yes, please add "WORSENING" in the AE term. If not, kindly remove this entry. Otherwise, clarify in query response.' answered with 'Updated per query request' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	23 Oct 2020 14:59:20
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	23 Oct 2020 14:59:12
User entered 'Worsening HYPERTENSION' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	23 Oct 2020 14:59:12
User opened query 'Per DM CLR: RQ: Response noted, however, the term was reverted to "HYPERTENSTION" only. Please review and verify if this is a worsening of the Med History condition. If yes, please add "WORSENING" in the AE term. If not, kindly remove this entry. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:59:29

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Generated On: 11 Aug 2021 22:52:44

Adverse event

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 08:34:19
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:43:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:43:53
Data point term sent to Coder	System	30 Sep 2020 18:42:51
Coding entries removed.	Heather Douds (b) (4) (b) (4)	30 Sep 2020 18:42:34
User entered 'HYPERTENSION' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	30 Sep 2020 18:42:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:55:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:55:55
Data point term sent to Coder	System	30 Sep 2020 17:55:08
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'Updated to worsening hypertension' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 17:54:31
Coding entries removed.		30 Sep 2020 17:54:16
User entered 'Worsening HYPERTENSION' reason for change: Per Query Resolution		30 Sep 2020 17:54:16

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Generated On: 11 Aug 2021 22:52:44

Adverse event

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 01:52:05
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:14:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:14:27
Data point term sent to Coder	System	02 Sep 2020 14:12:57
User entered 'hypertension'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Folder: Adverse Events

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Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Folder: Adverse Events

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Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:14:04
User entered '1 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 14:15:22
User entered '14:07' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:15:22
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 14:11:57
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:52:44

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '01 Sep 2020 14:07'	System	10 Nov 2020 20:14:04
User entered '1 Sep 2020 14:07'	System	02 Sep 2020 14:15:22
User entered empty.	System	02 Sep 2020 14:11:57

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:56:40
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'AE ongoing, will update with end date when available' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 19:10:34
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 13:57:24
User entered 'Yes (Y)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:13:42
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Sep 2020 20:13:28
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:13:28
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Sep 2020 20:13:11
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty; reason for change New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:13:42
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Sep 2020 20:13:11
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 20:13:11
User entered '01 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:13:11
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Sep 2020 20:12:51
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	28 Sep 2020 20:13:50
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:13:50
User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	28 Sep 2020 20:13:42
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:13:45
User entered '16:36' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:13:45
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:13:28
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	28 Sep 2020 20:13:42
User entered '01 Sep 2020 16:36'	System	02 Sep 2020 20:13:45
User entered empty.	System	02 Sep 2020 14:11:57

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Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:12:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Folder: Adverse Events

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Form: Adverse Events (1)

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 09:48:11
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'will update' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 16:34:04
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	19 Nov 2020 16:33:50
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 16:33:50
User entered 'None (NONE)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Hypertension. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 05:23:08
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Hypertension. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' answered with 'alprazolam taken for worsening hypertension r/t anxiety' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	29 Dec 2020 22:23:22
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Hypertension. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 21:44:58
User entered '1'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:13:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:12:51
User entered 'Unknown (UNKNOWN)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '0'	System	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:52:44

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:52:44

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Per DM CLR: Please specify the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). 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)	02 Oct 2020 08:33:42
Query 'Per DM CLR: Please specify the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'unknown' (Site from DM).	Heather Douds (b) (4) (b) (4)	30 Sep 2020 18:42:44
User opened query 'Per DM CLR: Please specify the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). 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)	30 Sep 2020 01:52:27
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:14:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:14:43
Data point term sent to Coder	System	02 Sep 2020 14:13:59
User entered 'tachycardia'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 20:14:22
User entered '1 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 14:15:12
User entered '14:07' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:15:12
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 14:13:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '01 Sep 2020 14:07'	System	10 Nov 2020 20:14:22
User entered '1 Sep 2020 14:07'	System	02 Sep 2020 14:15:12
User entered empty.	System	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:56:50
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'AE ongoing, will update with end date when available' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 19:10:43
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 13:57:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:14:48
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:15:16
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty; reason for change New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:14:48
User entered '01 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:15:16
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty; reason for change New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:14:48
User entered '16:36' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:15:16
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	28 Sep 2020 20:14:48
User entered '01 Sep 2020 16:36'	System	02 Sep 2020 20:15:16
User entered empty.	System	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'None (NONE)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:52:44
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Per DM CLR: RQ: Response noted, however, please add this AE term to the indication field of the Con Med. Update and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:27:02
Query 'Per DM CLR: RQ: Response noted, however, please add this AE term to the indication field of the Con Med. Update and reconcile as appropriate.' answered with 'Updated per query request' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	23 Oct 2020 15:00:05
User opened query 'Per DM CLR: RQ: Response noted, however, please add this AE term to the indication field of the Con Med. Update and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:56:43
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		02 Oct 2020 08:34:03
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Please see con med #3' (Site from DM).	Heather Douds (b) (4) (b) (4)	30 Sep 2020 18:45:17
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 01:52:37
User entered '1'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:14:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:15:16
User entered 'Unknown (UNKNOWN)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '0'	System	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 14:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:52:44

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05

US3552273
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:52:44
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).		22 Mar 2021 11:50:15
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'subject refused to come in for illness visit. deviation captured and monitor notified' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	18 Mar 2021 21:45:57
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 16:33:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 17:12:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 17:12:48
Data point term sent to Coder	System	12 Feb 2021 16:57:55
User entered 'DIARRHEA' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:59
Data point term sent to Coder	System	12 Feb 2021 16:56:54

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:52:44
Adverse event

Audit	User	Time (GMT)
User entered 'diarhea'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '08 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:48:30
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '14 Feb 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:48:30
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

US3552273

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

FDA-CBER-2022-1614-2714081

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

FDA-CBER-2022-1614-2714083

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:52:44
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:52:44

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '1'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:48:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '0'	System	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	12 Feb 2021 16:56:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:44

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:43:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:58:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:58:48
Data point term sent to Coder	System	03 Sep 2020 14:57:42
Coding entries removed.	Heather Douds (b) (4) (b) (4)	03 Sep 2020 14:57:17
User entered 'LISINOPRIL/hydrochlorothiazide' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	03 Sep 2020 14:57:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:32:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:32:54
Data point term sent to Coder	System	02 Sep 2020 17:31:57
Coding entries removed.	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:33
User entered 'LISINOPrIL' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:06:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:06:52
Data point term sent to Coder	System	02 Sep 2020 13:46:07
User entered 'lisinopail'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'hypertension'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '20 / 25'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'un UNK 1990'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '804 (804)'	System	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:47:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:47:52
Data point term sent to Coder	System	02 Sep 2020 13:47:10
User entered 'omeprazole'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'gastroesophageal reflux disease'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '40'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'un UNK 2019'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '804 (804)'	System	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 23:29:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 23:29:26
Data point term sent to Coder	System	29 Dec 2020 22:22:39
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	29 Dec 2020 22:22:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:05:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:05:41
Data point term sent to Coder	System	23 Oct 2020 15:00:42
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	23 Oct 2020 15:00:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:55:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:55:50
Data point term sent to Coder	System	02 Sep 2020 13:54:23
Data point term sent to Coder	System	02 Sep 2020 13:51:14
User entered 'alprazolam'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'ANXIETY AND TACHYCARDIA and worsening hypertension' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	29 Dec 2020 22:22:27
User closed query ' Per DM CLR: Please review the indication of TACHYCARDIA for this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 10:07:09
Query ' Per DM CLR: Please review the indication of TACHYCARDIA for this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'can be used for tachycardia related to anxiety. entered as reported by subject' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	18 Dec 2020 20:28:17
User opened query ' Per DM CLR: Please review the indication of TACHYCARDIA for this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 20:08:28
User entered 'ANXIETY and tachycardia' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	23 Oct 2020 15:00:30
User entered 'ANXIETY' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:16
User entered 'moderate anxiety'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

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US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '1'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'three times daily (TID)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record of Anxiety that match the indication. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 10:08:35
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record of Anxiety that match the indication. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify' answered with 'Med Hx #3' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	18 Dec 2020 20:28:58
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record of Anxiety that match the indication. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 20:08:37
User entered 'un UNK 2000'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '3'	System	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '804 (804)'	System	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: DESCOVY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:50:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:50:45
Data point term sent to Coder	System	02 Sep 2020 13:54:23
User entered 'doscovy'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'hiv prophylaxis'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '200/25'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'un UNK 2019'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '804 (804)'	System	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:57:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:57:52
Data point term sent to Coder	System	02 Sep 2020 13:56:30
User entered 'multivitamin'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)' reason for change: Per Query Cassandra Zehenny (b) (4) Resolution	(b) (4)	11 Nov 2020 16:26:11
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'health promotion'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '1'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'un Mar 2020'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:56:20

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '804 (804)'	System	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 13:44:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 13:44:12
Data point term sent to Coder	System	24 Nov 2020 13:42:58
Coding entries removed.	Stanley Doublin (b) (4) (b) (4)	24 Nov 2020 13:42:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 17:52:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 17:52:24
Data point term sent to Coder	System	19 Oct 2020 17:51:04
User entered 'influenza vaccine'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'INFLUENZA PROPHYLAXIS' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	24 Nov 2020 13:42:08
User entered 'prophylaxis'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '1'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Other (OTHER)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'injection'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '16 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '16 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:08:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:08:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
Data point term sent to Coder	System	11 Feb 2021 14:03:27
User entered 'metrodinazole'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'diarrhea'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '500'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'three times daily (TID)'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered empty.	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '10 Feb 2021'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '0'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:49:14
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '14 Feb 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:49:14
User entered empty.	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '3'	System	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '1'	System	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered '804 (804)'	System	11 Feb 2021 14:03:26

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:12:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:12:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
Data point term sent to Coder	System	02 Mar 2021 16:16:06
User entered 'Moderna EUA vaccine'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'COVID-19 prophylaxis'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered '1'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'Other (OTHER)'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'injection'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'once (ONCE)'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'Intramuscular (INTRAMUSCULAR)'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

FDA-CBER-2022-1614-2714236

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered '1 Mar 2021'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

FDA-CBER-2022-1614-2714240

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered '1 Mar 2021'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:52:44

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	02 Mar 2021 16:15:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User entered empty.	System	02 Mar 2021 16:15:14

US3552273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:52:44

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	18 Feb 2021 14:47:59

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:52:44

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered '28 Sep 2020'	Heather Douds (b) (4) (b) (4)	06 Oct 2020 14:05:14

US3552273

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:52:44

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User closed query 'Per CDM: it appears the AE of Anxiety caused the discontinuation. Please consider selecting 'Adverse Event (Specify) and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:49:18
User closed query 'Please verify if worsening anxiety (from baseline) should be captured as an AE, since this event lead to investigational product discontinuation. ' (Site from CRA).		19 Nov 2020 19:51:43
Query 'Please verify if worsening anxiety (from baseline) should be captured as an AE, since this event lead to investigational product discontinuation. ' answered with 'Anxiety is not an AE as already captured in medical history. Updated appropriately. ' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 16:34:48
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 16:34:26
User opened query 'Please verify if worsening anxiety (from baseline) should be captured as an AE, since this event lead to investigational product discontinuation. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 01:54:10
Query 'Per CDM: it appears the AE of Anxiety caused the discontinuation. Please consider selecting 'Adverse Event (Specify) and make all applicable updates.' answered with 'There is no anxiety AE, anxiety is a part of medical history. Entered correctly' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 17:59:56
User opened query 'Per CDM: it appears the AE of Anxiety caused the discontinuation. Please consider selecting 'Adverse Event (Specify) and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:17:39
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Heather Douds (b) (4) (b) (4)	06 Oct 2020 14:05:14

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:33:44
User entered 'AE #1' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 16:34:26
User entered 'Anxiety'	Heather Douds (b) (4) (b) (4)	06 Oct 2020 14:05:14

US3552273

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:52:44

Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:33:29
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	15 Mar 2021 15:55:29
User entered '01 Mar 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	15 Mar 2021 15:55:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered '1 Mar 2021'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:16:58

US3552273
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:52:44
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User closed query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' (Site from DM).		24 Mar 2021 12:44:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:33:29
Query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Mar 2021 19:56:14
Signature has been broken.	Heather Douds (b) (4) (b) (4)	22 Mar 2021 19:56:09
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	22 Mar 2021 19:56:09
User opened query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:39:07
User closed query 'Per CDM: Reason for Discontinuation = Other, however in AE eCRF its mentioned as Investigational product is withdrawn due to AE#1. Please review and reconcile. Or else clarify.' (Site from DM).		17 Mar 2021 05:01:55
Query 'Per CDM: Reason for Discontinuation = Other, however in AE eCRF its mentioned as Investigational product is withdrawn due to AE#1. Please review and reconcile. Or else clarify.' answered with 'that was from part A of the study, not the open-label portion' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	15 Mar 2021 15:55:09
User opened query 'Per CDM: Reason for Discontinuation = Other, however in AE eCRF its mentioned as Investigational product is withdrawn due to AE#1. Please review and reconcile. Or else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:09:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14

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US3552273

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:52:44

Reason for discontinuation

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:16:58

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered 'Subject received EUA vaccine outside of study'	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:16:58

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:52:44

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:16:58

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Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:52:44
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:16:58

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Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:52:44
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:16:58

Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:52:44

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:13:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:58:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:16:58