

US3372274 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:17:38

All time stamps listed in this document are displayed in GMT

US3372274

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 19:46:54

Generated On: 09 Jun 2021 17:17:38

[Participant ID](#)

US3372274

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

US3372274

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:16:37

Generated On: 09 Jun 2021 17:17:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3372274

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 23:10:22

Generated On: 09 Jun 2021 17:17:38

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3372274

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 23:29:39

Generated On: 09 Jun 2021 17:17:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3372274

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 00:22:46

Generated On: 09 Jun 2021 17:17:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3372274

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 00:54:52

Generated On: 09 Jun 2021 17:17:38

Were any significant conditions reported?

Yes ☒

No ☐

US3372274

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372274

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1949
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1949
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1949
Start Year (derived)	1949
Stop Month and Year (derived)	JAN 1949
Stop Year (derived)	1949

US3372274

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 00:38:36

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:32:51

Generated On: 09 Jun 2021 17:17:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:30 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 14:30
Height (<i>xxx.x</i>)	161 cm
Weight (<i>xxx.x</i>)	71.1 kg
BMI (<i>xxx.x</i>)	27.42950 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372274

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:10:36

Generated On: 09 Jun 2021 17:17:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3372274

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:20:57

Generated On: 09 Jun 2021 17:17:38

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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3372274

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:20:57

Generated On: 09 Jun 2021 17:17:38

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	

US3372274

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:16:37

Generated On: 09 Jun 2021 17:17:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 02:04:12

Generated On: 09 Jun 2021 17:17:38

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188516

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 ☒

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:49:16

Generated On: 09 Jun 2021 17:17:38

Height	ND - Not Done
Weight	ND - Not Done

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:49:16

Generated On: 09 Jun 2021 17:17:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 14:30
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:49:16

Generated On: 09 Jun 2021 17:17:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 16:45
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3372274

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:10:36

Generated On: 09 Jun 2021 17:17:38

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.

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:46:49

Generated On: 09 Jun 2021 17:17:38

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 15:56 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 15:56

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

US3372274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:06:33

Generated On: 09 Jun 2021 17:17:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	15:15 (24 HR)
Collection date and time (derived)	27 AUG 2020 15:15

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:22:45

Generated On: 09 Jun 2021 17:17:38

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:15	27 AUG 2020 15:15
Nasopharyngeal Swab 2	No		

US3372274

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 16:49

PC Open Date & Time

27 AUG 2020 16:16

PC Close Date & Time

27 AUG 2020 18:46

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	27 AUG 2020 19:47
PC Open Date & Time	27 AUG 2020 19:41
PC Close Date & Time	28 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

28 AUG 2020 14:06

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:11

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

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

98.3 °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

30 AUG 2020 12:16

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

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

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

31 AUG 2020 12:21

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:26

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

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

27 AUG 2020 16:50

PC Open Date & Time

27 AUG 2020 16:16

PC Close Date & Time

27 AUG 2020 18:46

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

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

27 AUG 2020 19:48

PC Open Date & Time

27 AUG 2020 19:41

PC Close Date & Time

28 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 14:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:11

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:17

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:22

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:27

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:58

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

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 ☐

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 16:51
PC Open Date & Time	27 AUG 2020 16:16
PC Close Date & Time	27 AUG 2020 18:46

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

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 ☐

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 19:49
PC Open Date & Time	27 AUG 2020 19:41
PC Close Date & Time	28 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

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 ☒

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 14:08
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2563

EAB) (1725)

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:12
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2563

EAB) (1725)

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:18
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

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 ☒

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:22
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2563

EAB) (1725)

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:27
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2563

EAB) (1725)

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:59
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3372274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:25

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:25

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:25

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:23:53

Generated On: 09 Jun 2021 17:17:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:23:53

Generated On: 09 Jun 2021 17:17:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	09:01 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:01
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:23:53

Generated On: 09 Jun 2021 17:17:38

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:17
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3372274

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:23:53

Generated On: 09 Jun 2021 17:17:38

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.

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:23:53

Generated On: 09 Jun 2021 17:17:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 SEP 2020

What was the treatment time? (00:00-23:59) 09:43 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 09:43

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

US3372274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:23:53

Generated On: 09 Jun 2021 17:17:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	09:12 (24 HR)
Collection date and time (derived)	29 SEP 2020 09:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:22:45

Generated On: 09 Jun 2021 17:17:38

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:00	29 SEP 2020 09:00
Nasopharyngeal Swab 2	No		

US3372274

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 29 SEP 2020 10:17

PC Open Date & Time 29 SEP 2020 10:03

PC Close Date & Time 29 SEP 2020 12:33

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	29 SEP 2020 18:28
PC Open Date & Time	29 SEP 2020 13:28
PC Close Date & Time	30 SEP 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

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

30 SEP 2020 16:37

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:50

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

02 OCT 2020 14:45

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

03 OCT 2020 17:37

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:18

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 18:27

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 10:19

PC Open Date & Time

29 SEP 2020 10:03

PC Close Date & Time

29 SEP 2020 12:33

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 18:28

PC Open Date & Time

29 SEP 2020 13:28

PC Close Date & Time

30 SEP 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 16:38

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 12:50

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 14:46

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 17:38

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 12:18

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 18:27

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

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 ☐

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:20
PC Open Date & Time	29 SEP 2020 10:03
PC Close Date & Time	29 SEP 2020 12:33

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

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 ☐

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 18:29
PC Open Date & Time	29 SEP 2020 13:28
PC Close Date & Time	30 SEP 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 2563

EAB) (1725)

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 16:39
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2563

EAB) (1725)

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 12:51
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

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 ☒

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 14:46
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

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 ☒

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 17:38
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

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 ☒

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:19
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

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 ☒

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 18:28
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3372274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 13:45:41

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:25

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:25

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:04:39

Generated On: 09 Jun 2021 17:17:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:04:39

Generated On: 09 Jun 2021 17:17:38

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) _____

US3372274

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:04:39

Generated On: 09 Jun 2021 17:17:38

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.

US3372274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:04:39

Generated On: 09 Jun 2021 17:17:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	14:22 (24 HR)
Collection date and time (derived)	26 OCT 2020 14:22

US3372274

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

27 OCT 2020 12:53:53

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

04 NOV 2020 13:01:36

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

10 NOV 2020 08:59:59

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 07:36:12
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

05 DEC 2020 06:45:40

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 DEC 2020 07:01:46
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

19 DEC 2020 12:14:57

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 15:15:50

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 08:25:41
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

17 JAN 2021 13:51:53

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

24 JAN 2021 10:19:36

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

30 JAN 2021 07:22:46

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 07:37:06

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

14 FEB 2021 09:45:49

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

20 FEB 2021 09:16:22

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 07:15:06
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 MAR 2021 07:04:48
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 06:54:21

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 20:21:44

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 07:21:36

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 12:13:21

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 07:27:45
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 08:06:22

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 07:29:45
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

Patient Cloud Open Date & Time	05 JUN 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	09 JUN 2021 23:59
---	-------------------

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 369

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 537

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	09 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	04 JUN 2022 00:01
Patient Cloud Close Date & Time	08 JUN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	17 AUG 2022 23:59
---	-------------------

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3372274

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:17:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 07:15:18

US3372274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:25

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:25

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:25

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 22:50:20

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 22:50:20

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 21:47:18

Generated On: 09 Jun 2021 17:17:38

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

Visit date (dd MMM yyyy)	22 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:44:52

Generated On: 09 Jun 2021 17:17:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 14:10
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	92 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	52 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372274

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 21:47:18

Generated On: 09 Jun 2021 17:17:38

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.

US3372274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 18:40:11

Generated On: 09 Jun 2021 17:17:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	22 MAR 2021 14:25

US3372274

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 21:47:18

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Feb 2021 23:03:56

Generated On: 09 Jun 2021 17:17:38

Date of Contact	23 DEC 2020
Time of Contact	13:40
Date and Time of Contact (derived)	23 DEC 2020 13:40
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

Symptom Day

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

325 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

326 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

Symptom Day

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

Date	24 DEC 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	97.9 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

329 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

Symptom Day

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		333 of 2563
EAB) (1725)		

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

334 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

Symptom Day

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

337 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

338 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

Symptom Day

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

Symptom Day

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 2563

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Feb 2021 02:55:16

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Feb 2021 23:01:24

Generated On: 09 Jun 2021 17:17:38

Date of Visit	23 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	23 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Feb 2021 23:59:28

Generated On: 09 Jun 2021 17:17:38

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Mar 2021 13:33:34

Generated On: 09 Jun 2021 17:17:38

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 DEC 2020
Day 5	Yes	27 DEC 2020
Day 7	Yes	29 DEC 2020
Day 9		
Day 14		
Day 21		
Day 28		

US3372274

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:16:37

Generated On: 09 Jun 2021 17:17:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:32:51

Generated On: 09 Jun 2021 17:17:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	13:45 (24 HR)
Vital Signs Date and Time (derived)	23 DEC 2020 13:45
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	157.5 lb
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	93 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372274

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:10:36

Generated On: 09 Jun 2021 17:17:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 DEC 2020

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

US3372274

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Feb 2021 17:13:57

Generated On: 09 Jun 2021 17:17:38

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 DEC 2020

US3372274

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:16:37

Generated On: 09 Jun 2021 17:17:38

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

Visit date (dd MMM yyyy)	11 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3372274

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 21:37:10

Generated On: 09 Jun 2021 17:17:38

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	11 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3372274

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:49:15

Generated On: 09 Jun 2021 17:17:38

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

US3372274

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:49:15

Generated On: 09 Jun 2021 17:17:38

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 12:14
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3372274

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:49:15

Generated On: 09 Jun 2021 17:17:38

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 13:00
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3372274

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

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:10:36

Generated On: 09 Jun 2021 17:17:38

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.

US3372274

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:46:49

Generated On: 09 Jun 2021 17:17:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 JAN 2021

What was the treatment time? (00:00-23:59) 12:28 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 12:28

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

US3372274

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:06:33

Generated On: 09 Jun 2021 17:17:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	11:53 (24 HR)
Collection date and time (derived)	11 JAN 2021 11:53

US3372274

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 17:41:40

Generated On: 09 Jun 2021 17:17:38

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

Collection date (dd MMM yyyy)	11 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	11:51
---------------------------------	-------

Collection Date and Time (derived)	11 JAN 2021 11:51
------------------------------------	-------------------

US3372274

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:28

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:16:37

Generated On: 09 Jun 2021 17:17:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:49:15

Generated On: 09 Jun 2021 17:17:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 09:00
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:49:15

Generated On: 09 Jun 2021 17:17:38

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 10:20
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3372274

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:10:36

Generated On: 09 Jun 2021 17:17:38

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.

US3372274

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:46:49

Generated On: 09 Jun 2021 17:17:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 8 FEB 2021

What was the treatment time? (00:00-23:59) 09:48 (24 HR)

Treatment Date and Time (derived) 8 FEB 2021 09:48

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

US3372274

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:28

Generated On: 09 Jun 2021 17:17:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372274

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:07

Generated On: 09 Jun 2021 17:17:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372274

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 21:47:17

Generated On: 09 Jun 2021 17:17:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 21:47:18

Generated On: 09 Jun 2021 17:17:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 14:10
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	92 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	52 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372274

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 21:47:17

Generated On: 09 Jun 2021 17:17:38

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.

US3372274

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 18:40:11

Generated On: 09 Jun 2021 17:17:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	22 MAR 2021 14:25

US3372274

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:48:11

Generated On: 09 Jun 2021 17:17:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

AEID	USA-US056-2020-MRNA-1273-P30 1000010
Adverse event	MYOCARDIAL INFARCT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	14 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 2563

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

SUBJECT ADMITTED TO
HOSPITAL WITH CHEST
PAIN-JAW PAIN. CAT SCAN
AND ECHOCARDIOGRAM
COMPLETED. RESULTS
UNKNOWN AT THIS TIME.
SUBJECT WAS DIAGNOSED
WITH MYOCARDIAL
INFARCTION. SUBJECT
DISCHARGED ON 14-DEC-2020.
MEDICAL RECORDS HAVE
BEEN REQUESTED.

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

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

AEID

Adverse event

CARDIAC CHEST PAIN

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)

13 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

383 of 2563

EAB) (1725)

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

AEID	
Adverse event	JAW PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2563

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

AEID

Adverse event

ATRIAL FIBRILLATION

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)

13 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

387 of 2563

EAB) (1725)

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 16:39:17

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 01:48:16

Generated On: 09 Jun 2021 17:17:38

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

Yes ☒

No ☐

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

390 of 2563

EAB) (1725)

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication DOXAZOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA (BPH)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

396 of 2563

EAB) (1725)

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	INFLUENZA PROPHYLAXIS/PREVENTION
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication PNEUMOVAX

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

400 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication HERPES ZOSTER VACCINE

Prophylaxis Yes ☒
No ☐

Indication HERPES ZOSTER
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication HERPES ZOSTER VACCINE

Prophylaxis Yes ☒
No ☐

Indication HERPES ZOSTER
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication ALFUZOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA (BPH)

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCT

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

410 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication HEPARIN SODIUM

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 3500

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2563

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication NITROGLYCERIN 2%

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 1

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

If dose unit is Other, specify PATCH

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

414 of 2563

EAB) (1725)

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

Name of Medication DILTIAZEM

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

416 of 2563

EAB) (1725)

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 13:21:01

Generated On: 09 Jun 2021 17:17:38

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

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 18:18:45

Generated On: 09 Jun 2021 17:17:38

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Feb 2021 18:08:58

Generated On: 09 Jun 2021 17:17:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 DEC 2020	CAT SCAN THORAX	Adverse Event	
13 DEC 2020	ELECTROCARDIOGRAM	Adverse Event	

US3372274

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:17:38

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3372274

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:17:38

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:39:18

Generated On: 09 Jun 2021 17:17:38

SAEID	USA-US056-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:39:18

Generated On: 09 Jun 2021 17:17:38

SAEID	USA-US056-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/DEC/2020 14:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 16:39:18

Generated On: 09 Jun 2021 17:17:38

SAEID	USA-US056-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/JAN/2021 11:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 16:39:18

Generated On: 09 Jun 2021 17:17:38

SAEID	USA-US056-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/JAN/2021 12:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 16:39:18

Generated On: 09 Jun 2021 17:17:38

SAEID	USA-US056-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Apr 2021 16:39:18

Generated On: 09 Jun 2021 17:17:38

SAEID	USA-US056-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/APR/2021 10:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (7)

Data signed: (b) (4) 22 Apr 2021 16:39:18

Generated On: 09 Jun 2021 17:17:38

SAEID	USA-US056-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/APR/2021 10:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3372274 (Prod: Palm Beach Research Center)

US3372274

Form: Participant Creation

Generated On: 09 Jun 2021 17:17:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:46:54
User entered 'US3372274'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:45:20

US3372274

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:23:54

US3372274

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:45:21

US3372274

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:23:54

US3372274

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'SCRN'	System	27 Aug 2020 20:23:54

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered (b) (6) 1943'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:45:22

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered '76'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'YEARS'	System	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '76'	System	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:17:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:10:22
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:19

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:29:40
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Aug 2020'	System	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '2020'	System	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:29:40
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:29:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:29:40
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:29:40
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:29:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:42

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:29:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:45:21

US3372274

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'I'	System	27 Aug 2020 20:24:52

US3372274

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:24:52

US3372274

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:17:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:54:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:02:20

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:12:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:12:54
Data point term sent to Coder	System	16 Nov 2020 22:12:31
User entered 'benign prostatic hyperplasia (BPH)'	Peter Jacob (b) (4)	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered empty.	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Aug 2020'	System	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '2020'	System	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered empty.	System	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered empty.	System	16 Nov 2020 22:12:22

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:12:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:12:53
Data point term sent to Coder	System	16 Nov 2020 22:12:32
User entered 'hypercholesterolemia'	Peter Jacob (b) (4)	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered empty.	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 2017'	System	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '2017'	System	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered empty.	System	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered empty.	System	16 Nov 2020 22:12:30

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Double vessel bypass graft - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 07:23:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 07:23:16
Data point term sent to Coder	System	16 Nov 2020 22:13:32
User entered 'coronary artery bypass graft - double'	Peter Jacob (b) (4)	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1990'	System	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1990'	System	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1990'	System	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1990'	System	16 Nov 2020 22:12:52

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:13:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:13:49
Data point term sent to Coder	System	16 Nov 2020 22:13:32
User entered 'appendectomy'	Peter Jacob (b) (4)	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1954'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1954'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1954'	System	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1954'	System	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1954'	System	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1954'	System	16 Nov 2020 22:13:13

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:15:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:15:55
Data point term sent to Coder	System	16 Nov 2020 22:14:34
User entered 'tonsillectomy'	Peter Jacob (b) (4)	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1949'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1949'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1949'	System	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1949'	System	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1949'	System	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1949'	System	16 Nov 2020 22:13:53

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Umbilical hernia repair, LLT: Umbilical herniorrhaphy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:15:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:15:54
Data point term sent to Coder	System	16 Nov 2020 22:14:34
User entered 'umbilical herniorrhaphy'	Peter Jacob (b) (4)	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1990'	System	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1990'	System	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1990'	System	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1990'	System	16 Nov 2020 22:14:15

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Metabolic surgery, LLT: Bariatric surgery - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:18:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:18:48
Data point term sent to Coder	System	16 Nov 2020 22:18:39
User entered 'bariatric surgery'	Peter Jacob (b) (4)	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 2000'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 2000'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 2000'	System	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '2000'	System	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 2000'	System	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:17:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '2000'	System	16 Nov 2020 22:18:07

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:18:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:18:48
Data point term sent to Coder	System	16 Nov 2020 22:18:39
User entered 'umbilical hernia'	Peter Jacob (b) (4)	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1990'	System	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1990'	System	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1990'	System	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:17:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1990'	System	16 Nov 2020 22:18:21

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:20:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:20:47
Data point term sent to Coder	System	16 Nov 2020 22:19:39
User entered 'appendicitis'	Peter Jacob (b) (4)	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1954'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1954'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1954'	System	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1954'	System	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1954'	System	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:17:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1954'	System	16 Nov 2020 22:18:43

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:36:48
Data point term sent to Coder	System	16 Nov 2020 22:19:39
User entered 'coronary artery disease'	Peter Jacob (b) (4)	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1990'	System	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1990'	System	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 1990'	System	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:17:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '1990'	System	16 Nov 2020 22:19:05

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:21:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 22:21:47
Data point term sent to Coder	System	16 Nov 2020 22:20:40
User entered 'obesity'	Peter Jacob (b) (4)	16 Nov 2020 22:20:32
	(b) (4)	

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 2000'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered 'un UNK 2000'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:38:37
User entered '0'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 2000'	System	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '2000'	System	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'Jan 2000'	System	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:17:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '2000'	System	16 Nov 2020 22:20:32

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '14:30'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '27 Aug 2020 14:30'	System	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '161' cm	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 18:59:26
DataPoint set to visible.	(b) (4) System	27 Aug 2020 20:24:52

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '71.1' kg	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 18:59:26
DataPoint set to visible.	(b) (4) System	27 Aug 2020 20:24:52

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered '27.42950'	System	08 Sep 2020 18:59:26
DataPoint set to visible.	System	27 Aug 2020 20:24:52

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'kg/m2'	System	08 Sep 2020 18:59:26
DataPoint set to visible.	System	27 Aug 2020 20:24:52

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:08:19
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 14:28:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 14:28:26
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 11:50:41
User entered '36.3' C	Peter Jacob (b) (4) (b) (4)	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered empty; reason for change Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	28 Sep 2020 14:28:26
User entered 'Oral (Oral)'	(b) (4)	
	Peter Jacob (b) (4)	08 Sep 2020 18:59:26
	(b) (4)	

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 14:28:26
User entered '71'	Peter Jacob (b) (4)	08 Sep 2020 18:59:26
	(b) (4)	

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'bpm'	System	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 14:28:26
User entered '16'	Peter Jacob (b) (4)	08 Sep 2020 18:59:26
	(b) (4)	

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'breaths/min'	System	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 14:28:26
User entered '117'	Peter Jacob (b) (4)	08 Sep 2020 18:59:26
	(b) (4)	

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'mmHg'	System	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 14:28:26
User entered '67'	Peter Jacob (b) (4)	08 Sep 2020 18:59:26
	(b) (4)	

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User entered 'mmHg'	System	08 Sep 2020 18:59:26

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07

US3372274

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07

US3372274

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 18:59:35

US3372274

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 18:59:35

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'retired'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered '0'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered '0'	Peter Jacob (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

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)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered '0'	Peter Jacob (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:24:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:20:57
User entered empty.	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:00:57

US3372274

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:03:15

US3372274

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:03:15

US3372274

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Clinic (Clinic)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:03:15

US3372274

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'VISIT1'	System	08 Sep 2020 19:03:15

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:29:34

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User entered '188516'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:29:34

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:29:34

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

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)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:26:29

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

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)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:26:29

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:26:29

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:26:29

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:26:29

US3372274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:38

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:04:12
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:03:42
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	29 Oct 2020 16:53:47
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	29 Oct 2020 16:53:41
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:33:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:17:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:17:42

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:24:30
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 14:21:20
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 14:21:16
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 11:50:31
User entered '161' cm	Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 14:21:16
User entered '71.1' kg	Peter Jacob (b) (4)	08 Sep 2020 19:04:01
	(b) (4)	

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:24:30
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 14:21:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 14:21:16
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 11:50:31
User entered '161' cm	Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 14:21:16
User entered '71.1' kg	Peter Jacob (b) (4)	08 Sep 2020 19:04:01
	(b) (4)	

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '14:30'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered '27 Aug 2020 14:30'	System	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '36.3' C	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '71'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'bpm'	System	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'breaths/min'	System	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '117'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'mmHg'	System	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '67'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'mmHg'	System	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:24:30
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 14:21:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 14:21:16
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 11:50:31
User entered '161' cm	Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:01

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 14:21:16
User entered '71.1' kg	Peter Jacob (b) (4)	08 Sep 2020 19:04:01
	(b) (4)	

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '16:45'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered '27 Aug 2020 16:45'	System	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '36.1' C	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '72'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'bpm'	System	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'breaths/min'	System	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '103'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'mmHg'	System	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '60'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'mmHg'	System	08 Sep 2020 19:04:26

US3372274

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:34

US3372274

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:04:34

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

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)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered '15:56'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered '27 Aug 2020 15:56'	System	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'ONCE'	System	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 20:25:47

US3372274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:06:33
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:05:04

US3372274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:06:33
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:05:04

US3372274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:06:33
User entered '15:15'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:05:04

US3372274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered '27 Aug 2020 15:15'	System	08 Sep 2020 19:05:04

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:17:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered '27 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered '15:15'	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered '27 Aug 2020 15:15'	System	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered empty.	System	08 Sep 2020 19:05:13

US3372274

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	08 Sep 2020 16:46:18

US3372274

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'I'	System	08 Sep 2020 16:46:18

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:48:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '36cb1e79-64af-4316-a54a-a1d7cb4c8110' User entered 'Yes (Y)'	System	27 Aug 2020 20:49:18
	System	27 Aug 2020 20:49:18

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:49:01', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '36cb1e79-64af-4316-a54a-a1d7cb4c8110' User entered '96.9'	System	27 Aug 2020 20:49:18
	System	27 Aug 2020 20:49:18

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:49:08', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '36cb1e79-64af-4316-a54a-a1d7cb4c8110'	System	27 Aug 2020 20:49:18
User entered 'No (N)'	System	27 Aug 2020 20:49:18

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:49:16', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '36cb1e79-64af-4316-a54a-a1d7cb4c8110' User entered '27 Aug 2020 16:49'	System	27 Aug 2020 20:49:18
	System	27 Aug 2020 20:49:18

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 16:16'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 18:46'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:46:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'afe87854-0745-424a-8c20-c04c29a3e6c4' User entered 'Yes (Y)'	System	27 Aug 2020 23:47:44
	System	27 Aug 2020 23:47:44

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:46:56', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'afe87854-0745-424a-8c20-c04c29a3e6c4' User entered '98.2'	System	27 Aug 2020 23:47:44
	System	27 Aug 2020 23:47:44

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:47:04', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'afe87854-0745-424a-8c20-c04c29a3e6c4'	System	27 Aug 2020 23:47:44
User entered 'No (N)'	System	27 Aug 2020 23:47:44

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:47:21', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'afe87854-0745-424a-8c20-c04c29a3e6c4' User entered '27 Aug 2020 19:47'	System	27 Aug 2020 23:47:44
	System	27 Aug 2020 23:47:44

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 19:41'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 2'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:06:02', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd4d39f78-4fa7-47b3-bfd0-839b9aeb62dd' User entered 'Yes (Y)'	System	28 Aug 2020 18:06:19
	System	28 Aug 2020 18:06:19

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:05:45', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd4d39f78-4fa7-47b3-bfd0-839b9aeb62dd' User entered '97.1'	System	28 Aug 2020 18:06:19
	System	28 Aug 2020 18:06:19

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:05:52', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd4d39f78-4fa7-47b3-bfd0-839b9aeb62dd' User entered 'No (N)'	System	28 Aug 2020 18:06:19
	System	28 Aug 2020 18:06:19

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:06:14', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd4d39f78-4fa7-47b3-bfd0-839b9aeb62dd' User entered '28 Aug 2020 14:06'	System	28 Aug 2020 18:06:19
	System	28 Aug 2020 18:06:19

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 3'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:14', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0c684214-41d4-4c5f-88fc-2b9dff1f4be8' User entered 'Yes (Y)'	System	29 Aug 2020 16:11:29
	System	29 Aug 2020 16:11:29

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:19', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0c684214-41d4-4c5f-88fc-2b9dff1f4be8' User entered '95.9'	System	29 Aug 2020 16:11:29
	System	29 Aug 2020 16:11:29

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:22', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0c684214-41d4-4c5f-88fc-2b9dff1f4be8'	System	29 Aug 2020 16:11:29
User entered 'No (N)'	System	29 Aug 2020 16:11:29

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0c684214-41d4-4c5f-88fc-2b9dff1f4be8' User entered '29 Aug 2020 12:11'	System	29 Aug 2020 16:11:29
	System	29 Aug 2020 16:11:29

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 4'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:16:10', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8ca6adb-da43-4c7c-accb-92e9690b1402' User entered 'Yes (Y)'	System	30 Aug 2020 16:16:39
	System	30 Aug 2020 16:16:39

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:16:18', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8ca6adb-da43-4c7c-accb-92e9690b1402' User entered '98.3'	System	30 Aug 2020 16:16:39
	System	30 Aug 2020 16:16:39

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:16:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8ca6adb-da43-4c7c-accb-92e9690b1402'	System	30 Aug 2020 16:16:39
User entered 'No (N)'	System	30 Aug 2020 16:16:39

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:16:35', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8ca6adb-da43-4c7c-accb-92e9690b1402'	System	30 Aug 2020 16:16:39
User entered '30 Aug 2020 12:16'	System	30 Aug 2020 16:16:39

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 5'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:20:49', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '865ffc82-b060-4741-afc7-6c0eb4c9a9f5' User entered 'Yes (Y)'	System	31 Aug 2020 16:29:01
	System	31 Aug 2020 16:29:01

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:20:57', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '865ffc82-b060-4741-afc7-6c0eb4c9a9f5' User entered '96.0'	System	31 Aug 2020 16:29:01
	System	31 Aug 2020 16:29:01

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:21:04', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '865ffc82-b060-4741-afc7-6c0eb4c9a9f5'	System	31 Aug 2020 16:29:01
User entered 'No (N)'	System	31 Aug 2020 16:29:01

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:21:09', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '865ffc82-b060-4741-afc7-6c0eb4c9a9f5' User entered '31 Aug 2020 12:21'	System	31 Aug 2020 16:29:01
	System	31 Aug 2020 16:29:01

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 6'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:26:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '4ba9cae1-8d1f-4b52-a53c-24760971d8b7' User entered 'Yes (Y)'	System	01 Sep 2020 16:26:36
	System	01 Sep 2020 16:26:36

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:26:18', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '4ba9cae1-8d1f-4b52-a53c-24760971d8b7' User entered '98.2'	System	01 Sep 2020 16:26:36
	System	01 Sep 2020 16:26:36

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:26:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '4ba9cae1-8d1f-4b52-a53c-24760971d8b7' User entered 'No (N)'	System	01 Sep 2020 16:26:36
	System	01 Sep 2020 16:26:36

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:26:32', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '4ba9cae1-8d1f-4b52-a53c-24760971d8b7' User entered '01 Sep 2020 12:26'	System	01 Sep 2020 16:26:36
	System	01 Sep 2020 16:26:36

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 7'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:54:18', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8a300376-b95f-430f-95cd-d6969a2aa449' User entered 'Yes (Y)'	System	02 Sep 2020 23:57:36
	System	02 Sep 2020 23:57:36

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:57:11', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8a300376-b95f-430f-95cd-d6969a2aa449' User entered '98.1'	System	02 Sep 2020 23:57:36
	System	02 Sep 2020 23:57:36

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:57:24', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8a300376-b95f-430f-95cd-d6969a2aa449'	System	02 Sep 2020 23:57:36
User entered 'No (N)'	System	02 Sep 2020 23:57:36

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:57:31', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8a300376-b95f-430f-95cd-d6969a2aa449' User entered '02 Sep 2020 19:57'	System	02 Sep 2020 23:57:36
	System	02 Sep 2020 23:57:36

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:49:28', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '060e46c7-e13b-42f0-907d-ac4fc60b72c3' User entered 'None (1)'	System	27 Aug 2020 20:50:24
	System	27 Aug 2020 20:50:24

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:49:31', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '060e46c7-e13b-42f0-907d-ac4fc60b72c3' User entered 'No (N)'	System	27 Aug 2020 20:50:24
	System	27 Aug 2020 20:50:24

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:49:37', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '060e46c7-e13b-42f0-907d-ac4fc60b72c3'	System	27 Aug 2020 20:50:24
User entered 'No (N)'	System	27 Aug 2020 20:50:24

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:50:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '060e46c7-e13b-42f0-907d-ac4fc60b72c3' User entered 'None (1)'	System	27 Aug 2020 20:50:24
	System	27 Aug 2020 20:50:24

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:50:21', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '060e46c7-e13b-42f0-907d-ac4fc60b72c3' User entered '27 Aug 2020 16:50'	System	27 Aug 2020 20:50:24
	System	27 Aug 2020 20:50:24

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 16:16'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 18:46'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:47:37', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '74911c48-fc62-4151-9ff5-33012f79d736'	System	27 Aug 2020 23:48:43
User entered 'None (1)'	System	27 Aug 2020 23:48:43

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:47:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '74911c48-fc62-4151-9ff5-33012f79d736' User entered 'No (N)'	System	27 Aug 2020 23:48:43
	System	27 Aug 2020 23:48:43

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:47:54', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '74911c48-fc62-4151-9ff5-33012f79d736' User entered 'No (N)'	System	27 Aug 2020 23:48:43
	System	27 Aug 2020 23:48:43

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:48:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '74911c48-fc62-4151-9ff5-33012f79d736' User entered 'None (1)'	System	27 Aug 2020 23:48:43
	System	27 Aug 2020 23:48:43

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:48:41', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '74911c48-fc62-4151-9ff5-33012f79d736' User entered '27 Aug 2020 19:48'	System	27 Aug 2020 23:48:43
	System	27 Aug 2020 23:48:43

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 19:41'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 2'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:06:24', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7f2d435b-052f-40e7-817e-322b6407bca7' User entered 'None (1)'	System	28 Aug 2020 18:07:48
	System	28 Aug 2020 18:07:48

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:06:31', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7f2d435b-052f-40e7-817e-322b6407bca7' User entered 'No (N)'	System	28 Aug 2020 18:07:48
	System	28 Aug 2020 18:07:48

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:06:41', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7f2d435b-052f-40e7-817e-322b6407bca7' User entered 'No (N)'	System	28 Aug 2020 18:07:48
	System	28 Aug 2020 18:07:48

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:07:27', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7f2d435b-052f-40e7-817e-322b6407bca7' User entered 'None (1)'	System	28 Aug 2020 18:07:48
	System	28 Aug 2020 18:07:48

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:07:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7f2d435b-052f-40e7-817e-322b6407bca7' User entered '28 Aug 2020 14:07'	System	28 Aug 2020 18:07:48
	System	28 Aug 2020 18:07:48

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 3'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:29', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fd9f16b6-f00e-413e-8ebc-db3be5174f29'	System	29 Aug 2020 16:11:44
User entered 'None (1)'	System	29 Aug 2020 16:11:44

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:32', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fd9f16b6-f00e-413e-8ebc-db3be5174f29'	System	29 Aug 2020 16:11:44
User entered 'No (N)'	System	29 Aug 2020 16:11:44

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:35', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fd9f16b6-f00e-413e-8ebc-db3be5174f29' User entered 'No (N)'	System	29 Aug 2020 16:11:44
	System	29 Aug 2020 16:11:44

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:37', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fd9f16b6-f00e-413e-8ebc-db3be5174f29'	System	29 Aug 2020 16:11:44
User entered 'None (1)'	System	29 Aug 2020 16:11:44

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:40', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fd9f16b6-f00e-413e-8ebc-db3be5174f29' User entered '29 Aug 2020 12:11'	System	29 Aug 2020 16:11:44
	System	29 Aug 2020 16:11:44

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 4'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:16:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '559f7fba-2c9c-491d-a5ce-914ada33204f' User entered 'None (1)'	System	30 Aug 2020 16:17:29
	System	30 Aug 2020 16:17:29

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:16:48', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '559f7fba-2c9c-491d-a5ce-914ada33204f' User entered 'No (N)'	System	30 Aug 2020 16:17:29
	System	30 Aug 2020 16:17:29

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:16:56', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '559f7fba-2c9c-491d-a5ce-914ada33204f' User entered 'No (N)'	System	30 Aug 2020 16:17:29
	System	30 Aug 2020 16:17:29

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:17:13', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '559f7fba-2c9c-491d-a5ce-914ada33204f' User entered 'None (1)'	System	30 Aug 2020 16:17:29
	System	30 Aug 2020 16:17:29

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:17:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '559f7fba-2c9c-491d-a5ce-914ada33204f' User entered '30 Aug 2020 12:17'	System	30 Aug 2020 16:17:29
	System	30 Aug 2020 16:17:29

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 5'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:21:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1379081-48de-4577-aa54-a1b1e8efe6a2'	System	31 Aug 2020 16:29:23
User entered 'None (1)'	System	31 Aug 2020 16:29:23

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:21:29', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1379081-48de-4577-aa54-a1b1e8efe6a2' User entered 'No (N)'	System	31 Aug 2020 16:29:23
	System	31 Aug 2020 16:29:23

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:21:34', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1379081-48de-4577-aa54-a1b1e8efe6a2'	System	31 Aug 2020 16:29:23
User entered 'No (N)'	System	31 Aug 2020 16:29:23

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:21:47', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1379081-48de-4577-aa54-a1b1e8efe6a2' User entered 'None (1)'	System	31 Aug 2020 16:29:23
	System	31 Aug 2020 16:29:23

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:01', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1379081-48de-4577-aa54-a1b1e8efe6a2' User entered '31 Aug 2020 12:22'	System	31 Aug 2020 16:29:23
	System	31 Aug 2020 16:29:23

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 6'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:26:41', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0074b295-50f6-4ef9-ac24-9c20a0eb2621' User entered 'None (1)'	System	01 Sep 2020 16:27:17
	System	01 Sep 2020 16:27:17

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:26:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0074b295-50f6-4ef9-ac24-9c20a0eb2621' User entered 'No (N)'	System	01 Sep 2020 16:27:17
	System	01 Sep 2020 16:27:17

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:26:48', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0074b295-50f6-4ef9-ac24-9c20a0eb2621' User entered 'No (N)'	System	01 Sep 2020 16:27:17
	System	01 Sep 2020 16:27:17

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:01', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0074b295-50f6-4ef9-ac24-9c20a0eb2621' User entered 'None (1)'	System	01 Sep 2020 16:27:17
	System	01 Sep 2020 16:27:17

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0074b295-50f6-4ef9-ac24-9c20a0eb2621' User entered '01 Sep 2020 12:27'	System	01 Sep 2020 16:27:17
	System	01 Sep 2020 16:27:17

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 7'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:57:40', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5a13e807-56a1-437d-8c47-8f03f3907e4c' User entered 'None (1)'	System	02 Sep 2020 23:58:19
	System	02 Sep 2020 23:58:19

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:57:50', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5a13e807-56a1-437d-8c47-8f03f3907e4c' User entered 'No (N)'	System	02 Sep 2020 23:58:19
	System	02 Sep 2020 23:58:19

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:57:56', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5a13e807-56a1-437d-8c47-8f03f3907e4c' User entered 'No (N)'	System	02 Sep 2020 23:58:19
	System	02 Sep 2020 23:58:19

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:07', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5a13e807-56a1-437d-8c47-8f03f3907e4c' User entered 'None (1)'	System	02 Sep 2020 23:58:19
	System	02 Sep 2020 23:58:19

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:17', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5a13e807-56a1-437d-8c47-8f03f3907e4c' User entered '02 Sep 2020 19:58'	System	02 Sep 2020 23:58:19
	System	02 Sep 2020 23:58:19

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:50:31', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c9a770ac-2b33-46d7-ab0e-dca83fdb336'	System	27 Aug 2020 20:51:18
User entered 'None (0)'	System	27 Aug 2020 20:51:18

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:50:38', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c9a770ac-2b33-46d7-ab0e-dca83fdb336'	System	27 Aug 2020 20:51:18
User entered 'None (0)'	System	27 Aug 2020 20:51:18

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:50:42', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c9a770ac-2b33-46d7-ab0e-dca83fdb336'	System	27 Aug 2020 20:51:18
User entered 'None (0)'	System	27 Aug 2020 20:51:18

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:50:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c9a770ac-2b33-46d7-ab0e-dca83fdb336'	System	27 Aug 2020 20:51:18
User entered 'None (0)'	System	27 Aug 2020 20:51:18

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:50:50', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c9a770ac-2b33-46d7-ab0e-dca83fdb336' User entered 'None (0)'	System	27 Aug 2020 20:51:18
	System	27 Aug 2020 20:51:18

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:50:54', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c9a770ac-2b33-46d7-ab0e-dca83fdb336' User entered 'None (0)'	System	27 Aug 2020 20:51:18
	System	27 Aug 2020 20:51:18

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:51:06', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c9a770ac-2b33-46d7-ab0e-dca83fdb336'	System	27 Aug 2020 20:51:18
User entered 'No (N)'	System	27 Aug 2020 20:51:18

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T16:51:15', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c9a770ac-2b33-46d7-ab0e-dca83fdb336'	System	27 Aug 2020 20:51:18
User entered '27 Aug 2020 16:51'	System	27 Aug 2020 20:51:18

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 16:16'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 18:46'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:48:54', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1e499a3-e2d3-4090-902b-d8dd83919e70' User entered 'None (0)'	System	27 Aug 2020 23:49:57
	System	27 Aug 2020 23:49:57

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:49:04', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1e499a3-e2d3-4090-902b-d8dd83919e70' User entered 'None (0)'	System	27 Aug 2020 23:49:57
	System	27 Aug 2020 23:49:57

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:49:08', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1e499a3-e2d3-4090-902b-d8dd83919e70' User entered 'None (0)'	System	27 Aug 2020 23:49:57
	System	27 Aug 2020 23:49:57

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:49:16', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1e499a3-e2d3-4090-902b-d8dd83919e70' User entered 'None (0)'	System	27 Aug 2020 23:49:57
	System	27 Aug 2020 23:49:57

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:49:21', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1e499a3-e2d3-4090-902b-d8dd83919e70' User entered 'None (0)'	System	27 Aug 2020 23:49:57
	System	27 Aug 2020 23:49:57

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:49:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1e499a3-e2d3-4090-902b-d8dd83919e70' User entered 'None (0)'	System	27 Aug 2020 23:49:57
	System	27 Aug 2020 23:49:57

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:49:39', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1e499a3-e2d3-4090-902b-d8dd83919e70'	System	27 Aug 2020 23:49:57
User entered 'No (N)'	System	27 Aug 2020 23:49:57

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-27T19:49:55', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a1e499a3-e2d3-4090-902b-d8dd83919e70' User entered '27 Aug 2020 19:49'	System	27 Aug 2020 23:49:57
	System	27 Aug 2020 23:49:57

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '27 Aug 2020 19:41'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 2'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:08:08', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '88f0b1b6-a5f9-4cdb-85cb-0a4f6bc3ca1a' User entered 'None (0)'	System	28 Aug 2020 18:09:02
	System	28 Aug 2020 18:09:02

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:08:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '88f0b1b6-a5f9-4cdb-85cb-0a4f6bc3ca1a' User entered 'None (0)'	System	28 Aug 2020 18:09:02
	System	28 Aug 2020 18:09:02

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:08:22', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '88f0b1b6-a5f9-4cdb-85cb-0a4f6bc3ca1a' User entered 'None (0)'	System	28 Aug 2020 18:09:02
	System	28 Aug 2020 18:09:02

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:08:27', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '88f0b1b6-a5f9-4cdb-85cb-0a4f6bc3ca1a' User entered 'None (0)'	System	28 Aug 2020 18:09:02
	System	28 Aug 2020 18:09:02

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:08:31', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '88f0b1b6-a5f9-4cdb-85cb-0a4f6bc3ca1a' User entered 'None (0)'	System	28 Aug 2020 18:09:02
	System	28 Aug 2020 18:09:02

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:08:34', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '88f0b1b6-a5f9-4cdb-85cb-0a4f6bc3ca1a' User entered 'None (0)'	System	28 Aug 2020 18:09:02
	System	28 Aug 2020 18:09:02

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:08:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '88f0b1b6-a5f9-4cdb-85cb-0a4f6bc3ca1a' User entered 'No (N)'	System	28 Aug 2020 18:09:02
	System	28 Aug 2020 18:09:02

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-28T14:08:56', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '88f0b1b6-a5f9-4cdb-85cb-0a4f6bc3ca1a' User entered '28 Aug 2020 14:08'	System	28 Aug 2020 18:09:02
	System	28 Aug 2020 18:09:02

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 3'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:54', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2689ed1e-a961-49db-b2a6-5fe9c550b14f' User entered 'None (0)'	System	29 Aug 2020 16:12:13
	System	29 Aug 2020 16:12:13

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:56', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2689ed1e-a961-49db-b2a6-5fe9c550b14f' User entered 'None (0)'	System	29 Aug 2020 16:12:13
	System	29 Aug 2020 16:12:13

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:11:59', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2689ed1e-a961-49db-b2a6-5fe9c550b14f' User entered 'None (0)'	System	29 Aug 2020 16:12:13
	System	29 Aug 2020 16:12:13

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:12:01', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2689ed1e-a961-49db-b2a6-5fe9c550b14f' User entered 'None (0)'	System	29 Aug 2020 16:12:13
	System	29 Aug 2020 16:12:13

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:12:03', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2689ed1e-a961-49db-b2a6-5fe9c550b14f' User entered 'None (0)'	System	29 Aug 2020 16:12:13
	System	29 Aug 2020 16:12:13

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:12:05', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2689ed1e-a961-49db-b2a6-5fe9c550b14f' User entered 'None (0)'	System	29 Aug 2020 16:12:13
	System	29 Aug 2020 16:12:13

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:12:09', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2689ed1e-a961-49db-b2a6-5fe9c550b14f' User entered 'No (N)'	System	29 Aug 2020 16:12:13
	System	29 Aug 2020 16:12:13

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-29T12:12:11', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2689ed1e-a961-49db-b2a6-5fe9c550b14f' User entered '29 Aug 2020 12:12'	System	29 Aug 2020 16:12:13
	System	29 Aug 2020 16:12:13

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 4'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:17:33', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9fa7d237-9282-4447-8c23-0b0764a71a3b' User entered 'None (0)'	System	30 Aug 2020 16:18:30
	System	30 Aug 2020 16:18:30

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:17:38', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9fa7d237-9282-4447-8c23-0b0764a71a3b' User entered 'None (0)'	System	30 Aug 2020 16:18:30
	System	30 Aug 2020 16:18:30

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:17:42', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9fa7d237-9282-4447-8c23-0b0764a71a3b' User entered 'None (0)'	System	30 Aug 2020 16:18:30
	System	30 Aug 2020 16:18:30

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:17:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9fa7d237-9282-4447-8c23-0b0764a71a3b' User entered 'None (0)'	System	30 Aug 2020 16:18:30
	System	30 Aug 2020 16:18:30

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:17:49', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9fa7d237-9282-4447-8c23-0b0764a71a3b' User entered 'None (0)'	System	30 Aug 2020 16:18:30
	System	30 Aug 2020 16:18:30

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:17:53', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9fa7d237-9282-4447-8c23-0b0764a71a3b' User entered 'None (0)'	System	30 Aug 2020 16:18:30
	System	30 Aug 2020 16:18:30

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:18:07', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9fa7d237-9282-4447-8c23-0b0764a71a3b' User entered 'No (N)'	System	30 Aug 2020 16:18:30
	System	30 Aug 2020 16:18:30

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-30T12:18:26', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9fa7d237-9282-4447-8c23-0b0764a71a3b' User entered '30 Aug 2020 12:18'	System	30 Aug 2020 16:18:30
	System	30 Aug 2020 16:18:30

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 5'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:09', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b0b99e43-cdbf-47ab-be86-3a31fbcd4d0a' User entered 'None (0)'	System	31 Aug 2020 16:32:37
	System	31 Aug 2020 16:32:37

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b0b99e43-cdbf-47ab-be86-3a31fbcd4d0a' User entered 'None (0)'	System	31 Aug 2020 16:32:37
	System	31 Aug 2020 16:32:37

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:16', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b0b99e43-cdbf-47ab-be86-3a31fbcd4d0a' User entered 'None (0)'	System	31 Aug 2020 16:32:37
	System	31 Aug 2020 16:32:37

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:19', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b0b99e43-cdbf-47ab-be86-3a31fbcd4d0a' User entered 'None (0)'	System	31 Aug 2020 16:32:37
	System	31 Aug 2020 16:32:37

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:24', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b0b99e43-cdbf-47ab-be86-3a31fbcd4d0a' User entered 'None (0)'	System	31 Aug 2020 16:32:37
	System	31 Aug 2020 16:32:37

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:27', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b0b99e43-cdbf-47ab-be86-3a31fbcd4d0a' User entered 'None (0)'	System	31 Aug 2020 16:32:37
	System	31 Aug 2020 16:32:37

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:34', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b0b99e43-cdbf-47ab-be86-3a31fbcd4d0a' User entered 'No (N)'	System	31 Aug 2020 16:32:37
	System	31 Aug 2020 16:32:37

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-08-31T12:22:50', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b0b99e43-cdbf-47ab-be86-3a31fbcd4d0a' User entered '31 Aug 2020 12:22'	System	31 Aug 2020 16:32:37
	System	31 Aug 2020 16:32:37

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 6'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:18', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dbd3ea9f-98e7-4960-b525-11fcfaae4c4f' User entered 'None (0)'	System	01 Sep 2020 16:28:01
	System	01 Sep 2020 16:28:01

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:21', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dbd3ea9f-98e7-4960-b525-11fcfaae4c4f' User entered 'None (0)'	System	01 Sep 2020 16:28:01
	System	01 Sep 2020 16:28:01

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:24', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dbd3ea9f-98e7-4960-b525-11fcfaae4c4f' User entered 'None (0)'	System	01 Sep 2020 16:28:01
	System	01 Sep 2020 16:28:01

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:27', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dbd3ea9f-98e7-4960-b525-11fcfaae4c4f' User entered 'None (0)'	System	01 Sep 2020 16:28:01
	System	01 Sep 2020 16:28:01

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:31', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dbd3ea9f-98e7-4960-b525-11fcfaae4c4f' User entered 'None (0)'	System	01 Sep 2020 16:28:01
	System	01 Sep 2020 16:28:01

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:35', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dbd3ea9f-98e7-4960-b525-11fcfaae4c4f' User entered 'None (0)'	System	01 Sep 2020 16:28:01
	System	01 Sep 2020 16:28:01

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:43', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dbd3ea9f-98e7-4960-b525-11fcfaae4c4f' User entered 'No (N)'	System	01 Sep 2020 16:28:01
	System	01 Sep 2020 16:28:01

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-01T12:27:59', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dbd3ea9f-98e7-4960-b525-11fcfaae4c4f' User entered '01 Sep 2020 12:27'	System	01 Sep 2020 16:28:01
	System	01 Sep 2020 16:28:01

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 7'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:22', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '53a23612-b014-419c-b0e7-c89f6a50178e' User entered 'None (0)'	System	02 Sep 2020 23:59:10
	System	02 Sep 2020 23:59:10

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:26', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '53a23612-b014-419c-b0e7-c89f6a50178e' User entered 'None (0)'	System	02 Sep 2020 23:59:10
	System	02 Sep 2020 23:59:10

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:30', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '53a23612-b014-419c-b0e7-c89f6a50178e' User entered 'None (0)'	System	02 Sep 2020 23:59:10
	System	02 Sep 2020 23:59:10

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:34', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '53a23612-b014-419c-b0e7-c89f6a50178e' User entered 'None (0)'	System	02 Sep 2020 23:59:10
	System	02 Sep 2020 23:59:10

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:37', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '53a23612-b014-419c-b0e7-c89f6a50178e' User entered 'None (0)'	System	02 Sep 2020 23:59:10
	System	02 Sep 2020 23:59:10

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:40', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '53a23612-b014-419c-b0e7-c89f6a50178e' User entered 'None (0)'	System	02 Sep 2020 23:59:10
	System	02 Sep 2020 23:59:10

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:58:49', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '53a23612-b014-419c-b0e7-c89f6a50178e' User entered 'No (N)'	System	02 Sep 2020 23:59:10
	System	02 Sep 2020 23:59:10

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-02T19:59:08', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '53a23612-b014-419c-b0e7-c89f6a50178e' User entered '02 Sep 2020 19:59'	System	02 Sep 2020 23:59:10
	System	02 Sep 2020 23:59:10

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 20:25:47

US3372274

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	08 Sep 2020 16:46:56

US3372274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered '3 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	08 Sep 2020 16:46:56

US3372274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	08 Sep 2020 16:46:56

US3372274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) Alexandra Arango (b) (4)	08 Sep 2020 16:46:56

US3372274

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	08 Sep 2020 16:47:01

US3372274

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'I'	System	08 Sep 2020 16:47:01

US3372274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	10 Sep 2020 16:35:01

US3372274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered '10 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	10 Sep 2020 16:35:01

US3372274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	10 Sep 2020 16:35:01

US3372274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) Alexandra Arango (b) (4)	10 Sep 2020 16:35:01
	(b) (4)	

US3372274

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	10 Sep 2020 16:35:08

US3372274

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:29:04
User entered 'I'	System	10 Sep 2020 16:35:08

US3372274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:04:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:34

US3372274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:04:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:34

US3372274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:04:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:34

US3372274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:04:30
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:34

US3372274

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:04:30
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:24:09

US3372274

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:04:30
User entered 'I'	System	29 Sep 2020 13:24:09

US3372274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:35:29
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:01:32
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:43:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 13:24:45

US3372274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 29SEP2020 is reported underVisit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 08:03:37
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 29SEP2020 is reported underVisit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:01:38
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 29SEP2020 is reported underVisit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:30:45
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 13:24:45

US3372274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:24:45

US3372274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'VISIT2'	System	29 Sep 2020 13:24:45

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '29 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '09:01'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered '29 Sep 2020 09:01'	System	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '67'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'bpm'	System	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '14'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'breaths/min'	System	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '98'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'mmHg'	System	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:53:57
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:43
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		12 Nov 2020 22:18:35
User entered '57'	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'mmHg'	System	12 Nov 2020 22:18:35

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '29 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '10:17'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered '29 Sep 2020 10:17'	System	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '36.1' C	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '63'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'bpm'	System	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '14'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'breaths/min'	System	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '102'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'mmHg'	System	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:54:02
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:22
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		12 Nov 2020 22:19:17
User entered '59'	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'mmHg'	System	12 Nov 2020 22:19:17

US3372274

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:20:01

US3372274

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:20:01

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

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)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '09:43'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered '29 Sep 2020 09:43'	System	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'ONCE'	System	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 13:55:12

US3372274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:20:23

US3372274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '29 Sep 2020'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:20:23

US3372274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:23:53
User entered '09:12'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:20:23

US3372274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered '29 Sep 2020 09:12'	System	12 Nov 2020 22:20:23

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:17:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered '29 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered '09:00'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered '29 Sep 2020 09:00'	System	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:22:45
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered empty.	System	12 Nov 2020 22:20:32

US3372274

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	08 Oct 2020 16:37:48

US3372274

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered '1'	System	08 Oct 2020 16:37:48

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:17:19', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e910f8f4-d867-4362-afae-bdc787ad8edf' User entered 'Yes (Y)'	System	29 Sep 2020 14:17:58
	System	29 Sep 2020 14:17:58

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:17:42', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e910f8f4-d867-4362-afae-bdc787ad8edf' User entered '97.0'	System	29 Sep 2020 14:17:58
	System	29 Sep 2020 14:17:58

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:17:49', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e910f8f4-d867-4362-afae-bdc787ad8edf' User entered 'No (N)'	System	29 Sep 2020 14:17:58
	System	29 Sep 2020 14:17:58

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:17:57', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e910f8f4-d867-4362-afae-bdc787ad8edf' User entered '29 Sep 2020 10:17'	System	29 Sep 2020 14:17:58
	System	29 Sep 2020 14:17:58

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 10:03'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 12:33'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:27:55', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd6738af0-e9b4-472d-92b0-2e7015119048' User entered 'Yes (Y)'	System	29 Sep 2020 22:28:26
	System	29 Sep 2020 22:28:26

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:28:05', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd6738af0-e9b4-472d-92b0-2e7015119048' User entered '98.2'	System	29 Sep 2020 22:28:26
	System	29 Sep 2020 22:28:26

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:28:11', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd6738af0-e9b4-472d-92b0-2e7015119048' User entered 'No (N)'	System	29 Sep 2020 22:28:26
	System	29 Sep 2020 22:28:26

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:28:21', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd6738af0-e9b4-472d-92b0-2e7015119048'	System	29 Sep 2020 22:28:26
User entered '29 Sep 2020 18:28'	System	29 Sep 2020 22:28:26

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 13:28'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 2'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:37:36', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5b4610c3-5f4f-496d-b700-7b4675051b41' User entered 'Yes (Y)'	System	30 Sep 2020 20:37:58
	System	30 Sep 2020 20:37:58

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:37:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5b4610c3-5f4f-496d-b700-7b4675051b41' User entered '98.0'	System	30 Sep 2020 20:37:58
	System	30 Sep 2020 20:37:58

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:37:49', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5b4610c3-5f4f-496d-b700-7b4675051b41' User entered 'No (N)'	System	30 Sep 2020 20:37:58
	System	30 Sep 2020 20:37:58

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:37:56', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5b4610c3-5f4f-496d-b700-7b4675051b41' User entered '30 Sep 2020 16:37'	System	30 Sep 2020 20:37:58
	System	30 Sep 2020 20:37:58

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 3'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:49:51', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fa71e61-ddda-4eab-93df-6c703b9672f3' User entered 'Yes (Y)'	System	01 Oct 2020 16:50:15
	System	01 Oct 2020 16:50:15

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:49:58', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fa71e61-ddda-4eab-93df-6c703b9672f3' User entered '98.0'	System	01 Oct 2020 16:50:15
	System	01 Oct 2020 16:50:15

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:04', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fa71e61-ddda-4eab-93df-6c703b9672f3'	System	01 Oct 2020 16:50:15
User entered 'No (N)'	System	01 Oct 2020 16:50:15

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:10', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fa71e61-ddda-4eab-93df-6c703b9672f3' User entered '01 Oct 2020 12:50'	System	01 Oct 2020 16:50:15
	System	01 Oct 2020 16:50:15

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 4'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:45:14', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fb04d2c7-a425-4b40-87a0-c7aaa7be59ee' User entered 'Yes (Y)'	System	02 Oct 2020 18:45:43
	System	02 Oct 2020 18:45:43

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:45:26', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fb04d2c7-a425-4b40-87a0-c7aaa7be59ee' User entered '96.3'	System	02 Oct 2020 18:45:43
	System	02 Oct 2020 18:45:43

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:45:32', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fb04d2c7-a425-4b40-87a0-c7aaa7be59ee' User entered 'No (N)'	System	02 Oct 2020 18:45:43
	System	02 Oct 2020 18:45:43

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:45:39', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fb04d2c7-a425-4b40-87a0-c7aaa7be59ee' User entered '02 Oct 2020 14:45'	System	02 Oct 2020 18:45:43
	System	02 Oct 2020 18:45:43

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 5'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:37:10', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '568037de-7a43-4e4f-b000-ab000a7c0a3e' User entered 'Yes (Y)'	System	03 Oct 2020 21:37:31
	System	03 Oct 2020 21:37:31

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:37:17', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '568037de-7a43-4e4f-b000-ab000a7c0a3e' User entered '98.4'	System	03 Oct 2020 21:37:31
	System	03 Oct 2020 21:37:31

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:37:23', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '568037de-7a43-4e4f-b000-ab000a7c0a3e' User entered 'No (N)'	System	03 Oct 2020 21:37:31
	System	03 Oct 2020 21:37:31

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:37:29', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '568037de-7a43-4e4f-b000-ab000a7c0a3e' User entered '03 Oct 2020 17:37'	System	03 Oct 2020 21:37:31
	System	03 Oct 2020 21:37:31

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 6'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:02', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'eda9b270-e517-40e5-9bed-052de082d790' User entered 'Yes (Y)'	System	04 Oct 2020 16:18:20
	System	04 Oct 2020 16:18:20

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:08', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'eda9b270-e517-40e5-9bed-052de082d790' User entered '98.3'	System	04 Oct 2020 16:18:20
	System	04 Oct 2020 16:18:20

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'eda9b270-e517-40e5-9bed-052de082d790' User entered 'No (N)'	System	04 Oct 2020 16:18:20
	System	04 Oct 2020 16:18:20

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:17', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'eda9b270-e517-40e5-9bed-052de082d790' User entered '04 Oct 2020 12:18'	System	04 Oct 2020 16:18:20
	System	04 Oct 2020 16:18:20

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 7'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '14a548dd-61fc-451a-8d57-93ee01e021b5' User entered 'Yes (Y)'	System	05 Oct 2020 22:27:26
	System	05 Oct 2020 22:27:26

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:09', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '14a548dd-61fc-451a-8d57-93ee01e021b5' User entered '98.6'	System	05 Oct 2020 22:27:26
	System	05 Oct 2020 22:27:26

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:16', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '14a548dd-61fc-451a-8d57-93ee01e021b5' User entered 'No (N)'	System	05 Oct 2020 22:27:26
	System	05 Oct 2020 22:27:26

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:21', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '14a548dd-61fc-451a-8d57-93ee01e021b5' User entered '05 Oct 2020 18:27'	System	05 Oct 2020 22:27:26
	System	05 Oct 2020 22:27:26

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:18:13', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5748025d-3d43-4853-a98f-6fe8e62cb753'	System	29 Sep 2020 14:19:14
User entered 'None (1)'	System	29 Sep 2020 14:19:14

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:18:42', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5748025d-3d43-4853-a98f-6fe8e62cb753' User entered 'No (N)'	System	29 Sep 2020 14:19:14
	System	29 Sep 2020 14:19:14

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:18:49', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5748025d-3d43-4853-a98f-6fe8e62cb753' User entered 'No (N)'	System	29 Sep 2020 14:19:14
	System	29 Sep 2020 14:19:14

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:18:56', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5748025d-3d43-4853-a98f-6fe8e62cb753'	System	29 Sep 2020 14:19:14
User entered 'None (1)'	System	29 Sep 2020 14:19:14

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:19:10', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5748025d-3d43-4853-a98f-6fe8e62cb753' User entered '29 Sep 2020 10:19'	System	29 Sep 2020 14:19:14
	System	29 Sep 2020 14:19:14

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 10:03'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 12:33'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:28:34', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '13f68502-587b-4aef-9594-967e2492462d' User entered 'None (1)'	System	29 Sep 2020 22:29:13
	System	29 Sep 2020 22:29:13

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:28:38', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '13f68502-587b-4aef-9594-967e2492462d' User entered 'No (N)'	System	29 Sep 2020 22:29:13
	System	29 Sep 2020 22:29:13

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:28:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '13f68502-587b-4aef-9594-967e2492462d' User entered 'No (N)'	System	29 Sep 2020 22:29:13
	System	29 Sep 2020 22:29:13

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:28:51', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '13f68502-587b-4aef-9594-967e2492462d' User entered 'None (1)'	System	29 Sep 2020 22:29:13
	System	29 Sep 2020 22:29:13

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:28:58', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '13f68502-587b-4aef-9594-967e2492462d' User entered '29 Sep 2020 18:28'	System	29 Sep 2020 22:29:13
	System	29 Sep 2020 22:29:13

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 13:28'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 2'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:04', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dc0962bc-a5f9-4d1b-a42e-877f7d3ffbc1' User entered 'None (1)'	System	30 Sep 2020 20:38:32
	System	30 Sep 2020 20:38:32

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:09', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dc0962bc-a5f9-4d1b-a42e-877f7d3ffbc1' User entered 'No (N)'	System	30 Sep 2020 20:38:32
	System	30 Sep 2020 20:38:32

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:13', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dc0962bc-a5f9-4d1b-a42e-877f7d3ffbc1' User entered 'No (N)'	System	30 Sep 2020 20:38:32
	System	30 Sep 2020 20:38:32

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:19', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dc0962bc-a5f9-4d1b-a42e-877f7d3ffbc1' User entered 'None (1)'	System	30 Sep 2020 20:38:32
	System	30 Sep 2020 20:38:32

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:29', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dc0962bc-a5f9-4d1b-a42e-877f7d3ffbc1' User entered '30 Sep 2020 16:38'	System	30 Sep 2020 20:38:32
	System	30 Sep 2020 20:38:32

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 3'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:20', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9cd912fe-8e4e-4c13-a65e-d18fb1df552f' User entered 'None (1)'	System	01 Oct 2020 16:50:50
	System	01 Oct 2020 16:50:50

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:24', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9cd912fe-8e4e-4c13-a65e-d18fb1df552f' User entered 'No (N)'	System	01 Oct 2020 16:50:50
	System	01 Oct 2020 16:50:50

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:29', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9cd912fe-8e4e-4c13-a65e-d18fb1df552f' User entered 'No (N)'	System	01 Oct 2020 16:50:50
	System	01 Oct 2020 16:50:50

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:33', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9cd912fe-8e4e-4c13-a65e-d18fb1df552f' User entered 'None (1)'	System	01 Oct 2020 16:50:50
	System	01 Oct 2020 16:50:50

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:48', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9cd912fe-8e4e-4c13-a65e-d18fb1df552f' User entered '01 Oct 2020 12:50'	System	01 Oct 2020 16:50:50
	System	01 Oct 2020 16:50:50

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 4'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:45:45', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8496a3a-bc13-4084-9fb9-dbde48aab1a0'	System	02 Oct 2020 18:46:07
User entered 'None (1)'	System	02 Oct 2020 18:46:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:45:50', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8496a3a-bc13-4084-9fb9-dbde48aab1a0' User entered 'No (N)'	System	02 Oct 2020 18:46:07
	System	02 Oct 2020 18:46:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:45:54', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8496a3a-bc13-4084-9fb9-dbde48aab1a0' User entered 'No (N)'	System	02 Oct 2020 18:46:07
	System	02 Oct 2020 18:46:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:45:57', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8496a3a-bc13-4084-9fb9-dbde48aab1a0' User entered 'None (1)'	System	02 Oct 2020 18:46:07
	System	02 Oct 2020 18:46:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:04', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd8496a3a-bc13-4084-9fb9-dbde48aab1a0' User entered '02 Oct 2020 14:46'	System	02 Oct 2020 18:46:07
	System	02 Oct 2020 18:46:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 5'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:37:35', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '47e586c1-0a21-4eba-b3be-a21284970d6b' User entered 'None (1)'	System	03 Oct 2020 21:38:07
	System	03 Oct 2020 21:38:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:37:39', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '47e586c1-0a21-4eba-b3be-a21284970d6b' User entered 'No (N)'	System	03 Oct 2020 21:38:07
	System	03 Oct 2020 21:38:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:37:43', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '47e586c1-0a21-4eba-b3be-a21284970d6b' User entered 'No (N)'	System	03 Oct 2020 21:38:07
	System	03 Oct 2020 21:38:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:37:48', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '47e586c1-0a21-4eba-b3be-a21284970d6b' User entered 'None (1)'	System	03 Oct 2020 21:38:07
	System	03 Oct 2020 21:38:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:03', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '47e586c1-0a21-4eba-b3be-a21284970d6b' User entered '03 Oct 2020 17:38'	System	03 Oct 2020 21:38:07
	System	03 Oct 2020 21:38:07

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 6'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:27', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '1b28e1b8-17a3-46bf-9714-9942adca20cc' User entered 'None (1)'	System	04 Oct 2020 16:18:55
	System	04 Oct 2020 16:18:55

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:31', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '1b28e1b8-17a3-46bf-9714-9942adca20cc' User entered 'No (N)'	System	04 Oct 2020 16:18:55
	System	04 Oct 2020 16:18:55

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:35', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '1b28e1b8-17a3-46bf-9714-9942adca20cc' User entered 'No (N)'	System	04 Oct 2020 16:18:55
	System	04 Oct 2020 16:18:55

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:40', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '1b28e1b8-17a3-46bf-9714-9942adca20cc' User entered 'None (1)'	System	04 Oct 2020 16:18:55
	System	04 Oct 2020 16:18:55

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:53', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '1b28e1b8-17a3-46bf-9714-9942adca20cc' User entered '04 Oct 2020 12:18'	System	04 Oct 2020 16:18:55
	System	04 Oct 2020 16:18:55

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 7'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:29', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e6e2e657-adb6-4329-9b0e-c3caa3b20aeb' User entered 'None (1)'	System	05 Oct 2020 22:27:49
	System	05 Oct 2020 22:27:49

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:32', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e6e2e657-adb6-4329-9b0e-c3caa3b20aeb' User entered 'No (N)'	System	05 Oct 2020 22:27:49
	System	05 Oct 2020 22:27:49

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:36', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e6e2e657-adb6-4329-9b0e-c3caa3b20aeb' User entered 'No (N)'	System	05 Oct 2020 22:27:49
	System	05 Oct 2020 22:27:49

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:41', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e6e2e657-adb6-4329-9b0e-c3caa3b20aeb' User entered 'None (1)'	System	05 Oct 2020 22:27:49
	System	05 Oct 2020 22:27:49

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:47', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e6e2e657-adb6-4329-9b0e-c3caa3b20aeb' User entered '05 Oct 2020 18:27'	System	05 Oct 2020 22:27:49
	System	05 Oct 2020 22:27:49

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:19:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fcd91f8-cb84-45da-9012-54af8b4700a8' User entered 'None (0)'	System	29 Sep 2020 14:20:14
	System	29 Sep 2020 14:20:14

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:19:29', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fcd91f8-cb84-45da-9012-54af8b4700a8' User entered 'None (0)'	System	29 Sep 2020 14:20:14
	System	29 Sep 2020 14:20:14

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:19:33', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fcd91f8-cb84-45da-9012-54af8b4700a8' User entered 'None (0)'	System	29 Sep 2020 14:20:14
	System	29 Sep 2020 14:20:14

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:19:39', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fcd91f8-cb84-45da-9012-54af8b4700a8' User entered 'None (0)'	System	29 Sep 2020 14:20:14
	System	29 Sep 2020 14:20:14

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:19:43', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fcd91f8-cb84-45da-9012-54af8b4700a8' User entered 'None (0)'	System	29 Sep 2020 14:20:14
	System	29 Sep 2020 14:20:14

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:19:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fcd91f8-cb84-45da-9012-54af8b4700a8' User entered 'None (0)'	System	29 Sep 2020 14:20:14
	System	29 Sep 2020 14:20:14

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:19:52', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fcd91f8-cb84-45da-9012-54af8b4700a8' User entered 'No (N)'	System	29 Sep 2020 14:20:14
	System	29 Sep 2020 14:20:14

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T10:20:11', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7fcd91f8-cb84-45da-9012-54af8b4700a8' User entered '29 Sep 2020 10:20'	System	29 Sep 2020 14:20:14
	System	29 Sep 2020 14:20:14

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 10:03'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 12:33'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:29:05', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f746a861-da5d-4ec1-b4ff-0592786a409e' User entered 'None (0)'	System	29 Sep 2020 22:29:51
	System	29 Sep 2020 22:29:51

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:29:09', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f746a861-da5d-4ec1-b4ff-0592786a409e' User entered 'None (0)'	System	29 Sep 2020 22:29:51
	System	29 Sep 2020 22:29:51

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:29:13', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f746a861-da5d-4ec1-b4ff-0592786a409e' User entered 'None (0)'	System	29 Sep 2020 22:29:51
	System	29 Sep 2020 22:29:51

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:29:17', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f746a861-da5d-4ec1-b4ff-0592786a409e' User entered 'None (0)'	System	29 Sep 2020 22:29:51
	System	29 Sep 2020 22:29:51

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:29:22', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f746a861-da5d-4ec1-b4ff-0592786a409e' User entered 'None (0)'	System	29 Sep 2020 22:29:51
	System	29 Sep 2020 22:29:51

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:29:26', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f746a861-da5d-4ec1-b4ff-0592786a409e' User entered 'None (0)'	System	29 Sep 2020 22:29:51
	System	29 Sep 2020 22:29:51

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:29:36', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f746a861-da5d-4ec1-b4ff-0592786a409e' User entered 'No (N)'	System	29 Sep 2020 22:29:51
	System	29 Sep 2020 22:29:51

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-29T18:29:49', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f746a861-da5d-4ec1-b4ff-0592786a409e' User entered '29 Sep 2020 18:29'	System	29 Sep 2020 22:29:51
	System	29 Sep 2020 22:29:51

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '29 Sep 2020 13:28'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 2'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:36', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e2e3aa94-a228-4370-9538-24c033db6fbd' User entered 'None (0)'	System	30 Sep 2020 20:39:10
	System	30 Sep 2020 20:39:10

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:39', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e2e3aa94-a228-4370-9538-24c033db6fbd' User entered 'None (0)'	System	30 Sep 2020 20:39:10
	System	30 Sep 2020 20:39:10

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:42', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e2e3aa94-a228-4370-9538-24c033db6fbd' User entered 'None (0)'	System	30 Sep 2020 20:39:10
	System	30 Sep 2020 20:39:10

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:45', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e2e3aa94-a228-4370-9538-24c033db6fbd' User entered 'None (0)'	System	30 Sep 2020 20:39:10
	System	30 Sep 2020 20:39:10

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:48', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e2e3aa94-a228-4370-9538-24c033db6fbd' User entered 'None (0)'	System	30 Sep 2020 20:39:10
	System	30 Sep 2020 20:39:10

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:52', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e2e3aa94-a228-4370-9538-24c033db6fbd' User entered 'None (0)'	System	30 Sep 2020 20:39:10
	System	30 Sep 2020 20:39:10

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:38:57', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e2e3aa94-a228-4370-9538-24c033db6fbd' User entered 'No (N)'	System	30 Sep 2020 20:39:10
	System	30 Sep 2020 20:39:10

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-09-30T16:39:07', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e2e3aa94-a228-4370-9538-24c033db6fbd' User entered '30 Sep 2020 16:39'	System	30 Sep 2020 20:39:10
	System	30 Sep 2020 20:39:10

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 3'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:53', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6d095940-c464-42c3-aafa-5697e2f16d7a' User entered 'None (0)'	System	01 Oct 2020 16:51:29
	System	01 Oct 2020 16:51:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:50:58', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6d095940-c464-42c3-aafa-5697e2f16d7a' User entered 'None (0)'	System	01 Oct 2020 16:51:29
	System	01 Oct 2020 16:51:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:51:03', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6d095940-c464-42c3-aafa-5697e2f16d7a' User entered 'None (0)'	System	01 Oct 2020 16:51:29
	System	01 Oct 2020 16:51:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:51:07', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6d095940-c464-42c3-aafa-5697e2f16d7a' User entered 'None (0)'	System	01 Oct 2020 16:51:29
	System	01 Oct 2020 16:51:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:51:10', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6d095940-c464-42c3-aafa-5697e2f16d7a' User entered 'None (0)'	System	01 Oct 2020 16:51:29
	System	01 Oct 2020 16:51:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:51:13', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6d095940-c464-42c3-aafa-5697e2f16d7a' User entered 'None (0)'	System	01 Oct 2020 16:51:29
	System	01 Oct 2020 16:51:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:51:19', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6d095940-c464-42c3-aafa-5697e2f16d7a' User entered 'No (N)'	System	01 Oct 2020 16:51:29
	System	01 Oct 2020 16:51:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-01T12:51:28', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6d095940-c464-42c3-aafa-5697e2f16d7a' User entered '01 Oct 2020 12:51'	System	01 Oct 2020 16:51:29
	System	01 Oct 2020 16:51:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 4'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:11', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8603b294-8647-4814-b5c1-09af1a9140b1' User entered 'None (0)'	System	02 Oct 2020 18:46:48
	System	02 Oct 2020 18:46:48

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:39', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8603b294-8647-4814-b5c1-09af1a9140b1' User entered 'None (0)'	System	02 Oct 2020 18:46:48
	System	02 Oct 2020 18:46:48

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:17', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8603b294-8647-4814-b5c1-09af1a9140b1' User entered 'None (0)'	System	02 Oct 2020 18:46:48
	System	02 Oct 2020 18:46:48

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:21', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8603b294-8647-4814-b5c1-09af1a9140b1' User entered 'None (0)'	System	02 Oct 2020 18:46:48
	System	02 Oct 2020 18:46:48

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8603b294-8647-4814-b5c1-09af1a9140b1' User entered 'None (0)'	System	02 Oct 2020 18:46:48
	System	02 Oct 2020 18:46:48

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:28', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8603b294-8647-4814-b5c1-09af1a9140b1' User entered 'None (0)'	System	02 Oct 2020 18:46:48
	System	02 Oct 2020 18:46:48

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:34', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8603b294-8647-4814-b5c1-09af1a9140b1' User entered 'No (N)'	System	02 Oct 2020 18:46:48
	System	02 Oct 2020 18:46:48

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-02T14:46:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '8603b294-8647-4814-b5c1-09af1a9140b1' User entered '02 Oct 2020 14:46'	System	02 Oct 2020 18:46:48
	System	02 Oct 2020 18:46:48

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 5'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a362feb7-c7c9-4737-afb0-fe8dbdd46fce' User entered 'None (0)'	System	03 Oct 2020 21:38:42
	System	03 Oct 2020 21:38:42

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:15', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a362feb7-c7c9-4737-afb0-fe8dbdd46fce' User entered 'None (0)'	System	03 Oct 2020 21:38:42
	System	03 Oct 2020 21:38:42

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:18', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a362feb7-c7c9-4737-afb0-fe8dbdd46fce' User entered 'None (0)'	System	03 Oct 2020 21:38:42
	System	03 Oct 2020 21:38:42

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:22', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a362feb7-c7c9-4737-afb0-fe8dbdd46fce' User entered 'None (0)'	System	03 Oct 2020 21:38:42
	System	03 Oct 2020 21:38:42

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:25', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a362feb7-c7c9-4737-afb0-fe8dbdd46fce' User entered 'None (0)'	System	03 Oct 2020 21:38:42
	System	03 Oct 2020 21:38:42

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:29', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a362feb7-c7c9-4737-afb0-fe8dbdd46fce' User entered 'None (0)'	System	03 Oct 2020 21:38:42
	System	03 Oct 2020 21:38:42

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:35', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a362feb7-c7c9-4737-afb0-fe8dbdd46fce' User entered 'No (N)'	System	03 Oct 2020 21:38:42
	System	03 Oct 2020 21:38:42

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-03T17:38:39', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a362feb7-c7c9-4737-afb0-fe8dbdd46fce' User entered '03 Oct 2020 17:38'	System	03 Oct 2020 21:38:42
	System	03 Oct 2020 21:38:42

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 6'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:18:58', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c73d03f3-050f-4f6e-bc5a-daa22724ae4e' User entered 'None (0)'	System	04 Oct 2020 16:19:31
	System	04 Oct 2020 16:19:31

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:19:01', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c73d03f3-050f-4f6e-bc5a-daa22724ae4e' User entered 'None (0)'	System	04 Oct 2020 16:19:31
	System	04 Oct 2020 16:19:31

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:19:04', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c73d03f3-050f-4f6e-bc5a-daa22724ae4e' User entered 'None (0)'	System	04 Oct 2020 16:19:31
	System	04 Oct 2020 16:19:31

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:19:07', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c73d03f3-050f-4f6e-bc5a-daa22724ae4e' User entered 'None (0)'	System	04 Oct 2020 16:19:31
	System	04 Oct 2020 16:19:31

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:19:10', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c73d03f3-050f-4f6e-bc5a-daa22724ae4e' User entered 'None (0)'	System	04 Oct 2020 16:19:31
	System	04 Oct 2020 16:19:31

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:19:13', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c73d03f3-050f-4f6e-bc5a-daa22724ae4e' User entered 'None (0)'	System	04 Oct 2020 16:19:31
	System	04 Oct 2020 16:19:31

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:19:20', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c73d03f3-050f-4f6e-bc5a-daa22724ae4e' User entered 'No (N)'	System	04 Oct 2020 16:19:31
	System	04 Oct 2020 16:19:31

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-04T12:19:27', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c73d03f3-050f-4f6e-bc5a-daa22724ae4e' User entered '04 Oct 2020 12:19'	System	04 Oct 2020 16:19:31
	System	04 Oct 2020 16:19:31

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	29 Sep 2020 13:55:12
User entered 'Day 7'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:52', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b33b6cf4-8cc1-4e3b-b7d4-284a1df86d83' User entered 'None (0)'	System	05 Oct 2020 22:28:29
	System	05 Oct 2020 22:28:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:55', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b33b6cf4-8cc1-4e3b-b7d4-284a1df86d83' User entered 'None (0)'	System	05 Oct 2020 22:28:29
	System	05 Oct 2020 22:28:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:27:57', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b33b6cf4-8cc1-4e3b-b7d4-284a1df86d83' User entered 'None (0)'	System	05 Oct 2020 22:28:29
	System	05 Oct 2020 22:28:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:28:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b33b6cf4-8cc1-4e3b-b7d4-284a1df86d83' User entered 'None (0)'	System	05 Oct 2020 22:28:29
	System	05 Oct 2020 22:28:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:28:05', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b33b6cf4-8cc1-4e3b-b7d4-284a1df86d83' User entered 'None (0)'	System	05 Oct 2020 22:28:29
	System	05 Oct 2020 22:28:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:28:13', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b33b6cf4-8cc1-4e3b-b7d4-284a1df86d83' User entered 'None (0)'	System	05 Oct 2020 22:28:29
	System	05 Oct 2020 22:28:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:28:21', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b33b6cf4-8cc1-4e3b-b7d4-284a1df86d83' User entered 'No (N)'	System	05 Oct 2020 22:28:29
	System	05 Oct 2020 22:28:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-05T18:28:24', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b33b6cf4-8cc1-4e3b-b7d4-284a1df86d83' User entered '05 Oct 2020 18:28'	System	05 Oct 2020 22:28:29
	System	05 Oct 2020 22:28:29

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:55:12

US3372274

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:17:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:55:12

US3372274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Oct 2020 16:38:08

US3372274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:05
User signature succeeded.	Mira Baron (b) (4)	30 Apr 2021 13:45:41
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 03:12:52
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered. call was placed 1 day to early' (Site from System).	Mary Sergalis (b) (4)	29 Apr 2021 15:21:32
User closed query 'Visits Safety Call Day 36 and Safety Call Day 43 are both dated 08OCT2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:44:58
Query 'Visits Safety Call Day 36 and Safety Call Day 43 are both dated 08OCT2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' answered with 'data updated per source' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 20:05:29
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Apr 2021 20:04:20
Signature has been broken.	(b) (4), (b) (6)	25 Apr 2021 20:04:20
User entered '1 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Apr 2021 20:04:20

US3372274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Visits Safety Call Day 36 and Safety Call Day 43 are both dated 08OCT2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 10:08:14
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered '8 Oct 2020'	(b) (4) Danielle Theodore (b) (4)	08 Oct 2020 16:38:08
	(b) (4)	

US3372274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Oct 2020 16:38:08

US3372274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) Danielle Theodore (b) (4)	08 Oct 2020 16:38:08
	(b) (4)	

US3372274

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:53:12
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	08 Oct 2020 16:38:19
	(b) (4)	

US3372274

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:53:12
User entered 'I'	System	08 Oct 2020 16:38:19

US3372274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Oct 2020 16:38:33

US3372274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:21:33
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'per CRA window was based off of visit 1 date before new amendment' (Site from System).	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:17:01
User entered '08 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 22:16:45
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 16:38:33
User entered '8 Oct 2020'	Danielle Theodore (b) (4) (b) (4)	08 Oct 2020 16:38:33

US3372274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	08 Oct 2020 16:38:33

US3372274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Oct 2020 16:38:33

US3372274

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	08 Oct 2020 16:39:03
	(b) (4)	

US3372274

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'I'	System	08 Oct 2020 16:39:03

US3372274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	16 Oct 2020 15:45:18

US3372274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:59:51
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol.' (Site from System).	Alexandra Arango (b) (4) (b) (4)	16 Oct 2020 15:45:34
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Oct 2020 15:45:18
User entered '15 Oct 2020'	Alexandra Arango (b) (4) (b) (4)	16 Oct 2020 15:45:18

US3372274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	16 Oct 2020 15:45:18

US3372274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) Alexandra Arango (b) (4)	16 Oct 2020 15:45:18
	(b) (4)	

US3372274

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	16 Oct 2020 15:45:43

US3372274

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'I'	System	16 Oct 2020 15:45:43

US3372274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 23 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 10:41:49
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 23 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:16:29
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 23 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:37:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 18:47:17

US3372274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:47:17

US3372274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:47:17

US3372274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'VISIT3'	System	26 Oct 2020 18:47:17

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered 'No (N)'	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered empty.	System	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered empty.	System	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered empty.	System	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered empty.	System	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered empty.	System	27 Oct 2020 19:02:44

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42

US3372274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42

US3372274

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered 'No (N)'	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:48

US3372274

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered empty.	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:02:48

US3372274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered 'Yes (Y)'	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:03:13

US3372274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered '26 Oct 2020'	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:03:13

US3372274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:04:39
User entered '14:22'	(b) (4) Jennifer Torres (b) (4)	27 Oct 2020 19:03:13

US3372274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered '26 Oct 2020 14:22'	System	27 Oct 2020 19:03:13

US3372274

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:47:27

US3372274

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'I'	System	26 Oct 2020 18:47:27

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 64'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-27T12:53:23', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2b5b7062-9a83-422b-85c3-a4786ff50be2' User entered 'No (N)'	System	27 Oct 2020 16:53:58
	System	27 Oct 2020 16:53:58

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with 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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-27T12:53:41', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2b5b7062-9a83-422b-85c3-a4786ff50be2'	System	27 Oct 2020 16:53:58
User entered 'No (N)'	System	27 Oct 2020 16:53:58

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-10-27T12:53:53', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '2b5b7062-9a83-422b-85c3-a4786ff50be2' User entered '27 Oct 2020 12:53:53'	System	27 Oct 2020 16:53:58
	System	27 Oct 2020 16:53:58

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 71'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-04T13:01:07', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dad6ae1f-3df1-4912-ab4f-73106a7596d7' User entered 'No (N)'	System	04 Nov 2020 18:01:38
	System	04 Nov 2020 18:01:38

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with 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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-04T13:01:23', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dad6ae1f-3df1-4912-ab4f-73106a7596d7'	System	04 Nov 2020 18:01:38
User entered 'No (N)'	System	04 Nov 2020 18:01:38

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-04T13:01:36', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'dad6ae1f-3df1-4912-ab4f-73106a7596d7' User entered '04 Nov 2020 13:01:36'	System	04 Nov 2020 18:01:38
	System	04 Nov 2020 18:01:38

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered 'Day 78'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-10T08:59:22', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c72d4c86-ded6-4fc7-8663-349b8c17cf0d'	System	10 Nov 2020 14:00:05
User entered 'No (N)'	System	10 Nov 2020 14:00:05

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with 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)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-10T08:59:34', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c72d4c86-ded6-4fc7-8663-349b8c17cf0d'	System	10 Nov 2020 14:00:05
User entered 'No (N)'	System	10 Nov 2020 14:00:05

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-10T08:59:59', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c72d4c86-ded6-4fc7-8663-349b8c17cf0d' User entered '10 Nov 2020 08:59:59'	System	10 Nov 2020 14:00:05
	System	10 Nov 2020 14:00:05

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 20:25:47

US3372274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:07:31
Data entry locked.	System	27 Aug 2020 20:25:47
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 20:25:47

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-30T07:35:36', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9b9f7d97-1976-4674-9647-abc643c71977' User entered 'No (N)'	System	30 Nov 2020 12:36:17
	System	30 Nov 2020 12:36:17

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-30T07:35:45', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9b9f7d97-1976-4674-9647-abc643c71977'	System	30 Nov 2020 12:36:17
User entered 'No (N)'	System	30 Nov 2020 12:36:17

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-11-30T07:36:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '9b9f7d97-1976-4674-9647-abc643c71977' User entered '30 Nov 2020 07:36:12'	System	30 Nov 2020 12:36:17
	System	30 Nov 2020 12:36:17

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-05T06:45:06', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '36fd18c1-e3ce-4843-8c79-523478406470' User entered 'No (N)'	System	05 Dec 2020 11:45:42
	System	05 Dec 2020 11:45:42

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-05T06:45:13', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '36fd18c1-e3ce-4843-8c79-523478406470' User entered 'No (N)'	System	05 Dec 2020 11:45:42
	System	05 Dec 2020 11:45:42

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-05T06:45:40', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '36fd18c1-e3ce-4843-8c79-523478406470' User entered '05 Dec 2020 06:45:40'	System	05 Dec 2020 11:45:42
	System	05 Dec 2020 11:45:42

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-15T07:00:09', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b591f9a5-6ba8-4222-9a5c-6f22a8fcac27'	System	15 Dec 2020 12:01:55
User entered 'Yes (Y)'	System	15 Dec 2020 12:01:55

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-15T07:00:20', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b591f9a5-6ba8-4222-9a5c-6f22a8fcac27'	System	15 Dec 2020 12:01:55
User entered 'No (N)'	System	15 Dec 2020 12:01:55

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-15T07:00:35', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b591f9a5-6ba8-4222-9a5c-6f22a8fcac27'	System	15 Dec 2020 12:01:55
User entered 'No (N)'	System	15 Dec 2020 12:01:55

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-15T07:01:12', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b591f9a5-6ba8-4222-9a5c-6f22a8fcac27'	System	15 Dec 2020 12:01:55
User entered 'Yes (Y)'	System	15 Dec 2020 12:01:55

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-15T07:01:35', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b591f9a5-6ba8-4222-9a5c-6f22a8fcac27'	System	15 Dec 2020 12:01:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Dec 2020 12:01:55

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-15T07:01:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b591f9a5-6ba8-4222-9a5c-6f22a8fcac27' User entered '15 Dec 2020 07:01:46'	System	15 Dec 2020 12:01:55
	System	15 Dec 2020 12:01:55

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-19T12:14:34', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd7592a35-accf-4da6-84c5-c0c899036ad4' User entered 'No (N)'	System	19 Dec 2020 17:15:00
	System	19 Dec 2020 17:15:00

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-19T12:14:41', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd7592a35-accf-4da6-84c5-c0c899036ad4' User entered 'No (N)'	System	19 Dec 2020 17:15:00
	System	19 Dec 2020 17:15:00

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2020-12-19T12:14:57', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'd7592a35-accf-4da6-84c5-c0c899036ad4' User entered '19 Dec 2020 12:14:57'	System	19 Dec 2020 17:15:00
	System	19 Dec 2020 17:15:00

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-04T15:15:19', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e5e92839-76c0-462f-9ac6-6adbb0613697' User entered 'No (N)'	System	04 Jan 2021 20:15:54
	System	04 Jan 2021 20:15:54

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-04T15:15:27', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e5e92839-76c0-462f-9ac6-6adbb0613697' User entered 'No (N)'	System	04 Jan 2021 20:15:54

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-04T15:15:50', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'e5e92839-76c0-462f-9ac6-6adbb0613697' User entered '04 Jan 2021 15:15:50'	System	04 Jan 2021 20:15:54
	System	04 Jan 2021 20:15:54

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-09T08:25:22', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '1837431c-94d1-462b-9e58-d5e1885f7cd8' User entered 'No (N)'	System	09 Jan 2021 13:25:44
	System	09 Jan 2021 13:25:44

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-09T08:25:30', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '1837431c-94d1-462b-9e58-d5e1885f7cd8'	System	09 Jan 2021 13:25:44
User entered 'No (N)'	System	09 Jan 2021 13:25:44

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-09T08:25:41', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '1837431c-94d1-462b-9e58-d5e1885f7cd8' User entered '09 Jan 2021 08:25:41'	System	09 Jan 2021 13:25:44

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-17T13:51:37', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6371d549-14cd-445f-8bdf-91ef3a624ec0' User entered 'No (N)'	System	17 Jan 2021 18:51:54
	System	17 Jan 2021 18:51:54

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-17T13:51:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6371d549-14cd-445f-8bdf-91ef3a624ec0' User entered 'No (N)'	System	17 Jan 2021 18:51:54

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-17T13:51:53', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '6371d549-14cd-445f-8bdf-91ef3a624ec0' User entered '17 Jan 2021 13:51:53'	System	17 Jan 2021 18:51:54
	System	17 Jan 2021 18:51:54

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-24T10:19:30', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '68f2ddd5-7fa8-4693-9dd1-49a93146ea9c' User entered 'No (N)'	System	24 Jan 2021 15:19:42

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-24T10:19:33', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '68f2ddd5-7fa8-4693-9dd1-49a93146ea9c' User entered 'No (N)'	System	24 Jan 2021 15:19:42

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-24T10:19:36', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '68f2ddd5-7fa8-4693-9dd1-49a93146ea9c' User entered '24 Jan 2021 10:19:36'	System	24 Jan 2021 15:19:42
	System	24 Jan 2021 15:19:42

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-30T07:22:41', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a866702a-7a9c-41ce-8b32-d922b821da2d' User entered 'No (N)'	System	30 Jan 2021 12:22:49
	System	30 Jan 2021 12:22:49

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-30T07:22:43', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a866702a-7a9c-41ce-8b32-d922b821da2d'	System	30 Jan 2021 12:22:49
User entered 'No (N)'	System	30 Jan 2021 12:22:49

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-01-30T07:22:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'a866702a-7a9c-41ce-8b32-d922b821da2d' User entered '30 Jan 2021 07:22:46'	System	30 Jan 2021 12:22:49
	System	30 Jan 2021 12:22:49

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-06T07:36:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0061f923-0ca4-4e33-b8ac-677e96503ba8' User entered 'No (N)'	System	06 Feb 2021 12:37:08
	System	06 Feb 2021 12:37:08

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-06T07:36:53', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0061f923-0ca4-4e33-b8ac-677e96503ba8' User entered 'No (N)'	System	06 Feb 2021 12:37:08
	System	06 Feb 2021 12:37:08

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-06T07:37:06', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '0061f923-0ca4-4e33-b8ac-677e96503ba8' User entered '06 Feb 2021 07:37:06'	System	06 Feb 2021 12:37:08
	System	06 Feb 2021 12:37:08

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-14T09:45:44', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '17bb0b72-9321-41c7-b011-c1c52046698c' User entered 'No (N)'	System	14 Feb 2021 14:45:51

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-14T09:45:46', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '17bb0b72-9321-41c7-b011-c1c52046698c' User entered 'No (N)'	System	14 Feb 2021 14:45:51

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-14T09:45:49', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '17bb0b72-9321-41c7-b011-c1c52046698c' User entered '14 Feb 2021 09:45:49'	System	14 Feb 2021 14:45:51
	System	14 Feb 2021 14:45:51

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-20T09:16:15', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '981e7976-0f07-4e3e-a7fa-d5674bd94058' User entered 'No (N)'	System	20 Feb 2021 14:16:24
	System	20 Feb 2021 14:16:24

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-20T09:16:18', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '981e7976-0f07-4e3e-a7fa-d5674bd94058' User entered 'No (N)'	System	20 Feb 2021 14:16:24

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-20T09:16:22', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '981e7976-0f07-4e3e-a7fa-d5674bd94058' User entered '20 Feb 2021 09:16:22'	System	20 Feb 2021 14:16:24
	System	20 Feb 2021 14:16:24

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-28T07:14:58-05:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '444365ae-bae7-40b0-a106-8c0c2068bfe9' User entered 'No (N)'	System	28 Feb 2021 12:15:10
	System	28 Feb 2021 12:15:10

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-28T07:15:02-05:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '444365ae-bae7-40b0-a106-8c0c2068bfe9' User entered 'No (N)'	System	28 Feb 2021 12:15:10
	System	28 Feb 2021 12:15:10

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-28T07:15:06-05:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '444365ae-bae7-40b0-a106-8c0c2068bfe9' User entered '28 Feb 2021 07:15:06'	System	28 Feb 2021 12:15:10
	System	28 Feb 2021 12:15:10

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-09T07:04:42-05:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b46e632f-f290-4874-afa0-2a1018c82836'	System	09 Mar 2021 12:04:53
User entered 'No (N)'	System	09 Mar 2021 12:04:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-09T07:04:44-05:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b46e632f-f290-4874-afa0-2a1018c82836'	System	09 Mar 2021 12:04:53
User entered 'No (N)'	System	09 Mar 2021 12:04:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-09T07:04:48-05:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b46e632f-f290-4874-afa0-2a1018c82836'	System	09 Mar 2021 12:04:53
User entered '09 Mar 2021 07:04:48'	System	09 Mar 2021 12:04:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-22T06:54:15-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'cca313ec-f44d-4219-ae38-e54de9e8bf04'	System	22 Mar 2021 10:54:25
User entered 'No (N)'	System	22 Mar 2021 10:54:25

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-22T06:54:18-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'cca313ec-f44d-4219-ae38-e54de9e8bf04'	System	22 Mar 2021 10:54:25
User entered 'No (N)'	System	22 Mar 2021 10:54:25

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-22T06:54:21-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'cca313ec-f44d-4219-ae38-e54de9e8bf04' User entered '22 Mar 2021 06:54:21'	System	22 Mar 2021 10:54:25
	System	22 Mar 2021 10:54:25

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-28T20:21:38-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5bfdfd64-d1a4-4f83-a2db-5f3bb096df7f' User entered 'No (N)'	System	29 Mar 2021 00:21:46

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-28T20:21:41-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5bfdfd64-d1a4-4f83-a2db-5f3bb096df7f' User entered 'No (N)'	System	29 Mar 2021 00:21:46

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-03-28T20:21:44-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '5bfdfd64-d1a4-4f83-a2db-5f3bb096df7f' User entered '28 Mar 2021 20:21:44'	System	29 Mar 2021 00:21:46

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-03T07:21:30-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7ff72c67-d6b7-477a-941b-acf7c3a343b4' User entered 'No (N)'	System	03 Apr 2021 11:21:40
	System	03 Apr 2021 11:21:40

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-03T07:21:32-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7ff72c67-d6b7-477a-941b-acf7c3a343b4'	System	03 Apr 2021 11:21:40
User entered 'No (N)'	System	03 Apr 2021 11:21:40

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-03T07:21:36-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: '7ff72c67-d6b7-477a-941b-acf7c3a343b4'	System	03 Apr 2021 11:21:40
User entered '03 Apr 2021 07:21:36'	System	03 Apr 2021 11:21:40

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-10T12:13:02-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fe808826-09d4-4969-ae96-92768435ed92'	System	10 Apr 2021 16:13:22
User entered 'No (N)'	System	10 Apr 2021 16:13:22

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-10T12:12:44-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fe808826-09d4-4969-ae96-92768435ed92'	System	10 Apr 2021 16:13:22
User entered 'No (N)'	System	10 Apr 2021 16:13:22

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-10T12:13:21-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'fe808826-09d4-4969-ae96-92768435ed92'	System	10 Apr 2021 16:13:22
User entered '10 Apr 2021 12:13:21'	System	10 Apr 2021 16:13:22

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-17T07:27:40-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f7ac089d-2d30-4240-8bbf-2f5d00d7e03b'	System	17 Apr 2021 11:27:49
User entered 'No (N)'	System	17 Apr 2021 11:27:49

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-17T07:27:43-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f7ac089d-2d30-4240-8bbf-2f5d00d7e03b' User entered 'No (N)'	System	17 Apr 2021 11:27:49

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-17T07:27:45-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'f7ac089d-2d30-4240-8bbf-2f5d00d7e03b' User entered '17 Apr 2021 07:27:45'	System	17 Apr 2021 11:27:49
	System	17 Apr 2021 11:27:49

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-24T08:06:16-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'edaed914-b693-44c5-b348-3002949a465e' User entered 'No (N)'	System	24 Apr 2021 12:06:25
	System	24 Apr 2021 12:06:25

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-24T08:06:19-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'edaed914-b693-44c5-b348-3002949a465e' User entered 'No (N)'	System	24 Apr 2021 12:06:25

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-04-24T08:06:22-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'edaed914-b693-44c5-b348-3002949a465e' User entered '24 Apr 2021 08:06:22'	System	24 Apr 2021 12:06:25
	System	24 Apr 2021 12:06:25

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-05-01T07:29:40-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b5da55de-1128-44e7-8061-7f64dcd52ad6'	System	01 May 2021 11:29:48
User entered 'No (N)'	System	01 May 2021 11:29:48

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-05-01T07:29:42-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b5da55de-1128-44e7-8061-7f64dcd52ad6'	System	01 May 2021 11:29:48
User entered 'No (N)'	System	01 May 2021 11:29:48

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-05-01T07:29:45-04:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'b5da55de-1128-44e7-8061-7f64dcd52ad6' User entered '01 May 2021 07:29:45'	System	01 May 2021 11:29:48
	System	01 May 2021 11:29:48

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:15:53

US3372274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:15:53
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:15:53

US3372274

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:17:38

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 07:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-28T07:15:13-05:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c5b7e9f4-4b00-4325-90c9-641a5ae2de3e' User entered 'No (N)'	System	28 Feb 2021 12:15:21
	System	28 Feb 2021 12:15:21

US3372274

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:17:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E8EAB77-B748-4E0D-844B-49DBF4748D17)', Time: '2021-02-28T07:15:18-05:00', User OID: 'PatientReportedOutcome (US3372274)', ODM File OID: 'c5b7e9f4-4b00-4325-90c9-641a5ae2de3e' User entered '28 Feb 2021 07:15:18'	System	28 Feb 2021 12:15:21
	System	28 Feb 2021 12:15:21

US3372274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 23DEC2020, however, this sample is missing in EDC. Please enter the 23DEC2020 Swab sample in the Covid-19 Assessment folder, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:32:49
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 23DEC2020, however, this sample is missing in EDC. Please enter the 23DEC2020 Swab sample in the Covid-19 Assessment folder, as appropriate.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:58:22
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 23DEC2020, however, this sample is missing in EDC. Please enter the 23DEC2020 Swab sample in the Covid-19 Assessment folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 22:56:13
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4)	24 Nov 2020 16:49:14

US3372274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered '24 Nov 2020'	(b) (4) Danielle Theodore (b) (4)	24 Nov 2020 16:49:14
	(b) (4)	

US3372274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	24 Nov 2020 16:49:14
	(b) (4)	

US3372274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) Danielle Theodore (b) (4)	24 Nov 2020 16:49:14
	(b) (4)	

US3372274

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	24 Nov 2020 16:49:22

US3372274

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:42
User entered 'I'	System	24 Nov 2020 16:49:22

US3372274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	28 Dec 2020 20:18:49

US3372274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered '28 Dec 2020'	(b) (4) Danielle Theodore (b) (4)	28 Dec 2020 20:18:49

US3372274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	28 Dec 2020 20:18:49

US3372274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	28 Dec 2020 20:18:49

US3372274

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	28 Dec 2020 20:18:54

US3372274

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User entered 'I'	System	28 Dec 2020 20:18:54

US3372274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 17:27:06

US3372274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered '27 Jan 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 17:27:06

US3372274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 17:27:06

US3372274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:25
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 17:27:06

US3372274

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Jan 2021 17:28:33

US3372274

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User entered 'I'	System	27 Jan 2021 17:28:33

US3372274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 22:50:20
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Feb 2021 14:26:58

US3372274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 22:50:20
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 11:43:45
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date correct as entered' (Site from System).	Danielle Theodore (b) (4) (b) (4)	22 Feb 2021 14:27:28
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Feb 2021 14:26:58
User entered '22 Feb 2021'	Danielle Theodore (b) (4) (b) (4)	22 Feb 2021 14:26:58

US3372274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 22:50:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Feb 2021 14:26:58

US3372274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 22:50:20
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Feb 2021 14:26:58

US3372274

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 22:50:20
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Feb 2021 14:31:36

US3372274

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:49
User entered 'I'	System	22 Feb 2021 14:31:36

US3372274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:25

US3372274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:25

US3372274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:25

US3372274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User entered 'VISIT4'	System	23 Mar 2021 15:32:25

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
User closed query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 07:11:59
Query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 20:11:31
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User opened query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:04:16
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered '14:10' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User entered '22 Mar 2021 14:10'	System	07 Apr 2021 20:09:52
User entered empty.	System	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered '36.6' C reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered 'Forehead' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
Signature has been broken.	(b) (4)	07 Apr 2021 20:09:52
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User entered 'bpm'	System	07 Apr 2021 20:09:52
User entered empty.	System	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User entered 'breaths/min'	System	07 Apr 2021 20:09:52
User entered empty.	System	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User entered 'mmHg'	System	07 Apr 2021 20:09:52
User entered empty.	System	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:52
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 07:12:13
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 20:10:37
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		07 Apr 2021 20:09:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User entered '52' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:09:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User entered 'mmHg'	System	07 Apr 2021 20:09:52
User entered empty.	System	02 Apr 2021 19:08:35

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57

US3372274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57

US3372274

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:31

US3372274

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:31

US3372274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Please review "Was the sample collected" as two Immuno 5 Samples dated 22MAR2021 is recorded under Visit 04 Day 209 visit with Barcode: 1F617366629 & OL-3 Visit with 22MAR2021 with Barcode: 1F617015863 are present in PPD Central Lab as per latest Preclarus report, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:28:52
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:11
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Please review "Was the sample collected" as two Immuno 5 Samples dated 22MAR2021 is recorded under Visit 04 Day 209 visit with Barcode: 1F617366629 & OL-3 Visit with 22MAR2021 with Barcode: 1F617015863 are present in PPD Central Lab as per latest Preclarus report, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit, else clarify.' answered with 'data updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:30:50
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 16:30:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 16:30:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Please review "Was the sample collected" as two Immuno 5 Samples dated 22MAR2021 is recorded under Visit 04 Day 209 visit with Barcode: 1F617366629 & OL-3 Visit with 22MAR2021 with Barcode: 1F617015863 are present in PPD Central Lab as per latest Preclarus report, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit, else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:14:01

US3372274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:42

US3372274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:11
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:30:37
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 16:30:37
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:42

US3372274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:11
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:30:37
User entered '14:25' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 16:30:37
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:42

US3372274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User entered '22 Mar 2021 14:25'	System	05 Apr 2021 16:30:37
User entered empty.	System	23 Mar 2021 15:32:42

US3372274

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:32:47

US3372274

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:21:57
User entered 'I'	System	23 Mar 2021 15:32:47

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:00
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:03:56
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:41:35

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:00
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:03:56
User entered '13:40'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:41:35

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:00
User entered '23 Dec 2020 13:40'	System	04 Jan 2021 21:41:35

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:00
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:03:56
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:41:35

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:00
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:03:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:41:35

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '96'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User entered '%'	System	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:17:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:43:15

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '93'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User entered '%'	System	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:17:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '25 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '97'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User entered '%'	System	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:17:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '26 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '97'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User entered '%'	System	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:17:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '27 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '97'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User entered '%'	System	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:17:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '97'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User entered '%'	System	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:17:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:55:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:49:27

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:01:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:17:38

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:11
User entered '0'	System	04 Jan 2021 21:51:14

US3372274

Folder: Covid-19 Assessment 23 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:17:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:16
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:59:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:19

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:17:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	04 Jan 2021 21:53:32

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:17:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	29 Mar 2021 13:33:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:53:32

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:17:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	29 Mar 2021 13:33:34
User entered '25 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:53:32

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:17:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	04 Jan 2021 21:53:53

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:17:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	29 Mar 2021 13:33:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:53:53

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:17:38

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 04:47:43
User signature succeeded.	Mira Baron (b) (4)	29 Mar 2021 13:33:34
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Data updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:33:26
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:04:06
User entered '27 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 21:53:53

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:17:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	26 Mar 2021 21:33:13

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:17:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	29 Mar 2021 13:33:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:33:13

US3372274

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:17:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	29 Mar 2021 13:33:34
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:33:13

US3372274

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:46

US3372274

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:46

US3372274

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Home (Home)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:51:46

US3372274

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User entered 'SICKD1'	System	04 Jan 2021 21:51:46

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '13:45'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User entered '23 Dec 2020 13:45'	System	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50
DataPoint set to visible.	System	04 Jan 2021 21:51:46

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '157.5' lb	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50
DataPoint set to visible.	System	04 Jan 2021 21:51:46

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered 'infrared forehead'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '79'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User entered 'bpm'	System	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '20'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User entered 'breaths/min'	System	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User entered '93'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User entered 'mmHg'	System	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:32:51
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 10:38:21
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Peter Jacob (b) (4) (b) (4)	05 Jan 2021 17:11:40
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		04 Jan 2021 21:52:50
User entered '59'	(b) (4), (b) (6)	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User entered 'mmHg'	System	04 Jan 2021 21:52:50

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05

US3372274

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05

US3372274

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:53:02

US3372274

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:53:02

US3372274

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:17:38

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:13:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:53:10

US3372274

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:17:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:49:05
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:13:57
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:53:10

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:25

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:25

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[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 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:25

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 19:03:25

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:00:58
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[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 00:41:44
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:37:10
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:40:42
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:08:56

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:00:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 05:56:44
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:37:10
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 17:40:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	12 Apr 2021 17:40:42
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:31:08
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:08:56

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:00:58
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:00:58
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:00:58
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:08:40
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:00:58
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:08:40
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:00:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered '1'	System	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'I'	System	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered empty.	System	14 Jan 2021 19:06:58
DataPoint set to visible.	System	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered empty.	System	14 Jan 2021 19:06:58
DataPoint set to visible.	System	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '12:14'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered '11 Jan 2021 12:14'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '58'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'bpm'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '12'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'breaths/min'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '103'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'mmHg'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '63'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'mmHg'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered empty.	System	14 Jan 2021 19:06:58
DataPoint set to visible.	System	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '13:00'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered '11 Jan 2021 13:00'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '67'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'bpm'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '12'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'breaths/min'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '127'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'mmHg'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '76'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'mmHg'	System	14 Jan 2021 19:06:58

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:07:03

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:07:03

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

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 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'mRNA-1273'	System	14 Jan 2021 19:07:21
DataPoint set to visible.	System	14 Jan 2021 19:03:44

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered '12:28'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered '11 Jan 2021 12:28'	System	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'ONCE'	System	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 19:07:21

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:06:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:56

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:06:33
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:56

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:06:33
User entered '11:53'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:03:56

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered '11 Jan 2021 11:53'	System	14 Jan 2021 19:03:56

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:41:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:10

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:17:38

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:41:41
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:10

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:17:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:41:41
User entered '11:51'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:10

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:17:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered '11 Jan 2021 11:51'	System	14 Jan 2021 19:04:10

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:04:15

US3372274

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'I'	System	14 Jan 2021 19:04:15

US3372274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:28
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	18 Jan 2021 16:30:20

US3372274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:28
User entered '18 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	18 Jan 2021 16:30:20
	(b) (4)	

US3372274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	18 Jan 2021 16:30:20

US3372274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:28
User entered empty.	(b) (4) Danielle Theodore (b) (4)	18 Jan 2021 16:30:20
	(b) (4)	

US3372274

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	18 Jan 2021 16:30:26

US3372274

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'I'	System	18 Jan 2021 16:30:26

US3372274

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered '1'	System	18 Jan 2021 16:30:26
DataPoint set to visible.	System	18 Jan 2021 16:30:26

US3372274

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:06:54

US3372274

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:06:54

US3372274

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[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 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:16:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:06:54

US3372274

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'OLD29'	System	08 Feb 2021 17:06:54

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '09:00'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered '8 Feb 2021 09:00'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '65'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'bpm'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'breaths/min'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '113'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'mmHg'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '64'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'mmHg'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '10:20'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered '8 Feb 2021 10:20'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '66'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'bpm'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'breaths/min'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '125'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'mmHg'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:49:16
User entered '68'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'mmHg'	System	08 Feb 2021 17:08:26

US3372274

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:34

US3372274

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:10:36
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:34

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

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 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'mRNA-1273'	System	08 Feb 2021 17:09:05
DataPoint set to visible.	System	18 Jan 2021 16:30:26

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered '09:48'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered '8 Feb 2021 09:48'	System	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:46:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'ONCE'	System	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 17:09:05

US3372274

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:09:09

US3372274

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'I'	System	08 Feb 2021 17:09:09

US3372274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:28
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Feb 2021 14:02:32

US3372274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:28
User entered '16 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	16 Feb 2021 14:02:32
	(b) (4)	

US3372274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Feb 2021 14:02:32

US3372274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:38:28
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Feb 2021 14:02:32

US3372274

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:01:07
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	16 Feb 2021 14:02:38
	(b) (4)	

US3372274

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:44
User entered 'I'	System	16 Feb 2021 14:02:38

US3372274

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:30:24

US3372274

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:30:24

US3372274

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[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 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:30:24

US3372274

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'OLD57'	System	23 Mar 2021 15:30:24

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '14:10'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered '22 Mar 2021 14:10'	System	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '62'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'bpm'	System	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'breaths/min'	System	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '92'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'mmHg'	System	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 12:00:49
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS for subject' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:52:32
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Mar 2021 15:31:26
User entered '52'	(b) (4), (b) (6)	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered 'mmHg'	System	23 Mar 2021 15:31:26

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36

US3372274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36

US3372274

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:46

US3372274

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:46

US3372274

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:11
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:30:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 16:30:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:57

US3372274

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:11
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:30:01
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 16:30:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:57

US3372274

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:11
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:30:01
User entered '14:25' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 16:30:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:31:57

US3372274

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:41:36
User entered '22 Mar 2021 14:25'	System	05 Apr 2021 16:30:01
User entered empty.	System	23 Mar 2021 15:31:57

US3372274

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:17:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:16
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:48:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:15
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	15 Dec 2020 13:44:17

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:39:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:06:02
User entered 'USA-US056-2020-mRNA-1273-P301000010'	System	15 Dec 2020 19:42:31
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 19:42:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 21:16:52
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarct - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 14:02:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	15 Dec 2020 14:02:57
User entered 'Myocardial Infarct'	(b) (4)	
	System	15 Dec 2020 14:02:32
	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:08:27
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:08:28
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:59
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:56
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:08:36
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	15 Dec 2020 14:03:08
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	15 Dec 2020 14:03:08
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	15 Dec 2020 14:02:31
User entered '10:00'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 14:03:08
User entered '13 Dec 2020 10:00'	System	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:08:34
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:43
User entered '14 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:45
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Dec 2020 14:03:08
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	15 Dec 2020 14:03:08
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Dec 2020 14:02:31
User entered '18:00'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 14:03:08
User entered '14 Dec 2020 18:00'	System	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:48
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:11:45
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:11:42
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:11:40
User entered 'I'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:11:37
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:28
User entered '14 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:30
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:34
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:36
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:38
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:16:39
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 21:16:33
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 16:56:37
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'done' (Site from Safety).	Mary Sergalis (b) (4)	23 Jan 2021 16:26:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	23 Jan 2021 16:26:27
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:12:50
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 11:44:17
User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 02:19:03
Query 'Please verify if this should be none as per CRF guidelines.' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 19:54:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Mar 2021 19:54:10
reason for change: Data Entry Error		
User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 21:18:14
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:44:20
User closed query 'PV Query: As the subject received both doses of the study Placebo, please update the action taken with study Placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 14:00:41
Query 'PV Query: As the subject received both doses of the study Placebo, please update the action taken with study Placebo from none to not applicable.' answered with 'Data updated.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 18:58:42
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 18:58:22
User opened query 'PV Query: As the subject received both doses of the study Placebo, please update the action taken with study Placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 13:33:51
User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 02:18:59
Query 'Please verify if this should be none as per CRF guidelines.' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 19:54:56
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:54:10
User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 21:18:22
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

None

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:17:09
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:17:11
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded was given AFTER the stop date of this AE. Please review and reconcile AE and CM start/stop dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:13:09
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded was given AFTER the stop date of this AE. Please review and reconcile AE and CM start/stop dates as appropriate. Otherwise, clarify.' answered with 'added' (Site from DM).	Mary Sergalis (b) (4)	23 Jan 2021 16:52:26
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded was given AFTER the stop date of this AE. Please review and reconcile AE and CM start/stop dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:46:32
User entered 'I'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:17:13
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:17:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:17:16
User entered empty.	Mary Sergalis (b) (4) 	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 20:54:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including EGG and echocardiogram) when available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 20:52:34
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:37:31
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including EGG and echocardiogram) when available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:37:26
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'hospital discharge summary was sent' (Site from Safety).	Peter Jacob (b) (4) (b) (4)	21 Apr 2021 20:24:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including EGG and echocardiogram) when available.' answered with 'data updated' (Site from Safety).	Peter Jacob (b) (4) (b) (4)	21 Apr 2021 20:23:33
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:17:27
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 20:38:44

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including EGG and echocardiogram) when available.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 20:38:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including EGG and echocardiogram) when available.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 16:56:48
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 16:56:42
User closed query 'Per DM CLR: SAE Narrative = CAT SCAN AND ECHOCARDIOGRAM COMPLETED. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:13:25
Query 'Per DM CLR: SAE Narrative = CAT SCAN AND ECHOCARDIOGRAM COMPLETED. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Mary Sergalis (b) (4)	23 Jan 2021 16:52:41
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including EGG and echocardiogram) when available.' answered with 'added' (Site from Safety).	Mary Sergalis (b) (4)	23 Jan 2021 16:52:36
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Not done' (Site from Safety).	Mary Sergalis (b) (4)	23 Jan 2021 16:29:48
User opened query 'Per DM CLR: SAE Narrative = CAT SCAN AND ECHOCARDIOGRAM COMPLETED. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:46:25

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including EGG and echocardiogram) when available.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:10:50
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:10:29
User entered 'Subject admitted to hospital with chest pain-jaw pain. CAT scan and Echocardiogram completed. Results unknown at this time. Subject was diagnosed with Myocardial Infarction. Subject discharged on 14-DEC-2020. Medical records have been requested.'	Mary Sergalis (b) (4)	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Dec 2020 14:02:31

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from Coder).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:18:39
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. 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)	18 Jan 2021 12:11:27
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 18:00:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 18:00:56
Data point term sent to Coder	System	15 Jan 2021 17:59:49
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'done' (Site from Coder).	Mary Sergalis (b) (4)	15 Jan 2021 17:59:47

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Specified' (Site from DM).	Mary Sergalis (b) (4)	15 Jan 2021 17:59:38
Coding entries removed.	Mary Sergalis (b) (4)	15 Jan 2021 17:59:27
User entered 'Cardiac CHEST PAIN' reason for change: Data Entry Error	Mary Sergalis (b) (4)	15 Jan 2021 17:59:27
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from Coder).	(b) (4), (b) (6)	29 Dec 2020 18:07:18
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. 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)	29 Dec 2020 08:10:42
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 14:06:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 14:06:59
Data point term sent to Coder	System	15 Dec 2020 14:05:33
User entered 'Chest Pain'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:18:43
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:18:45
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:18:46
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:18:48
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:18:51
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User entered empty.	System	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:18:52
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:18:54
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:42:01
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User entered empty.	System	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:18:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:42:04
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:12
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:14
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:16
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:17
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:27
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:28
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:30
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:31
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:33
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:24
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:19:23
User closed query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only if clinical event is prior to first dose of investigational product. Kindly review correctly and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 12:10:59
Query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only if clinical event is prior to first dose of investigational product. Kindly review correctly and reconcile as appropriate. ' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	15 Jan 2021 18:00:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	15 Jan 2021 17:59:27
User opened query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only if clinical event is prior to first dose of investigational product. Kindly review correctly and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 03:31:44
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 11:40:15
User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 11:40:02
Query 'Please verify if this should be none as per CRF guidelines.' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:00:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:00:18
User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 21:19:46
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:40:18
User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 11:40:05
Query 'Please verify if this should be none as per CRF guidelines.' answered with 'Data correct as is.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:01:03
User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 21:19:53
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:00
User entered 'l'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:02
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:03
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:06
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:08
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User entered '0'	System	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04
User entered 'I'	System	15 Dec 2020 14:04:52

US3372274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:04

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone related signs and symptoms, PT: Pain in jaw, LLT: Jaw pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 14:06:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 14:06:59
Data point term sent to Coder	System	15 Dec 2020 14:06:34
User entered 'Jaw Pain'	Mary Sergalis (b) (4) (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:37
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:20:39
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:31
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:29
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:33
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User entered empty.	System	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:35
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:36
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:38
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User entered empty.	System	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:41
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:45
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:47
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:49
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:50
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:52
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:53
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:55
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:56
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:58
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:01
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:07
User closed query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only if clinical event is prior to first dose of investigational product. Kindly review correctly and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:14:49
Query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only if clinical event is prior to first dose of investigational product. Kindly review correctly and reconcile as appropriate. ' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	23 Jan 2021 16:53:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	23 Jan 2021 16:53:09
User opened query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only if clinical event is prior to first dose of investigational product. Kindly review correctly and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 03:32:33
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 11:43:40
User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 11:43:28
Query 'Please verify if this should be none as per CRF guidelines.' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:02:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:01:57
User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 21:20:50
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:43:42
User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 11:43:30
Query 'Please verify if this should be none as per CRF guidelines.' answered with 'Data correct as is.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:02:37
User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 21:20:58
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:16
User entered 'l'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:18
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:19
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:21
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:45:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:45:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mary Sergalis (b) (4)	15 Dec 2020 14:45:03
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:05:40
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:23
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:24
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User entered '0'	System	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09
User entered 'I'	System	15 Dec 2020 14:05:40

US3372274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:09

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:21
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Jan 2021 16:53:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Jan 2021 16:53:07
Data point term sent to Coder	System	23 Jan 2021 16:52:06
User entered 'Atrial Fibrillation'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:23
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:28
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:32
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:36
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:38
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User entered empty.	System	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:40
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:41
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:43
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User entered empty.	System	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:46
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:48
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:49
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:51
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:52
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:05
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:03
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:02
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:00
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:21:58
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:11
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:09
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:13
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
User closed query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:25:00
Query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:04:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:03:44
User opened query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:58:55
User entered 'None (NONE)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:58
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:22:56
User entered 'l'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:02
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:04
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:23:12
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User entered '0'	System	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16
User entered 'I'	System	23 Jan 2021 16:52:04

US3372274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:55:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:17:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:24:37
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:23:55

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Nov 2020 22:29:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 22:29:48
Data point term sent to Coder	System	16 Nov 2020 22:28:46
User entered 'atorvastatin'	Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'hypercholesterolemia'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered '20'	Peter Jacob (b) (4)	16 Nov 2020 22:28:16
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:16
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:28:16
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:16
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:28:16
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:16
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:16
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 22:28:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:29:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:29:47
Data point term sent to Coder	System	16 Nov 2020 22:28:46
User entered 'aspirin'	Peter Jacob (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'cardiac prophylaxis'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '81'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:35
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:35
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:35
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2010'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 22:28:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:37:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:37:49
Data point term sent to Coder	System	16 Nov 2020 22:36:52
User entered 'doxazosin'	Peter Jacob (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'benign prostatic hyperplasia (BPH)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '24 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User entered '1'	System	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User entered '1'	System	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:32:24
User entered '804 (804)'	System	16 Nov 2020 22:36:28

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
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)	16 Nov 2020 22:39:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:39:48
Data point term sent to Coder	System	16 Nov 2020 22:38:54
User entered 'multivitamin'	Peter Jacob (b) (4)	16 Nov 2020 22:38:21

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:43:02
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'supplement is not an indication of prophylaxis ' (Site from DM).	Peter Jacob (b) (4) (b) (4)	03 Dec 2020 21:58:26
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:35:00
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "nutritional supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:46:35
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "nutritional supplement" and update if necessary. Thank you' answered with 'nutritional supplement is not an indication of prophylaxis' (Site from DM).	Peter Jacob (b) (4) (b) (4)	20 Nov 2020 15:02:57
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "nutritional supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:28:33
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:38:21

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'nutritional supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:38:21

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '1'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'capsule (CAPSULE)'	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:38:21

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:38:21

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'un UNK 2020'	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	16 Nov 2020 22:38:21
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:38:21

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:38:21

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 22:38:21

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
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)	16 Nov 2020 22:40:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:40:48
Data point term sent to Coder	System	16 Nov 2020 22:39:55
User entered 'influenza vaccine'	Peter Jacob (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User entered empty.	System	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User entered empty.	System	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:33:40
User entered empty.	System	16 Nov 2020 22:39:06

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:43:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:43:53
Data point term sent to Coder	System	16 Nov 2020 22:42:58
User entered 'pneumovax'	Peter Jacob (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'pneumonia prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User entered empty.	System	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User entered empty.	System	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:12
User entered empty.	System	16 Nov 2020 22:42:27

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:45:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:45:01
Data point term sent to Coder	System	16 Nov 2020 22:44:01
User entered 'herpes zoster vaccine'	Peter Jacob (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'herpes zoster prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User entered empty.	System	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User entered empty.	System	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:34:59
User entered empty.	System	16 Nov 2020 22:43:35

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:45:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:45:47
Data point term sent to Coder	System	16 Nov 2020 22:45:02
User entered 'herpes zoster vaccine'	Peter Jacob (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'herpes zoster prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User entered empty.	System	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User entered empty.	System	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:35:42
User entered empty.	System	16 Nov 2020 22:44:16

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: ALFUZOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Nov 2020 22:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 22:46:49
Data point term sent to Coder	System	16 Nov 2020 22:46:02
User entered 'alfuzosin'	Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:11

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'benign prostatic hyperplasia (BPH)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:11

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered '10'	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'once daily (QD)'	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:11

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered '24 Aug 2020'	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	16 Nov 2020 22:45:11
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:45:11

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:45:11

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 22:45:11

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
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)	16 Nov 2020 22:46:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:46:48
Data point term sent to Coder	System	16 Nov 2020 22:46:02
User entered 'influenza vaccine'	Peter Jacob (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered empty.	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:45:36
	(b) (4)	

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '17 Oct 2020'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered '17 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User entered empty.	System	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User entered empty.	System	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:15
User entered empty.	System	16 Nov 2020 22:45:36

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 21:28:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 14:07:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 14:07:51
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 14:07:34
User entered 'Eliquis'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:09
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:12
User entered 'Myocardial Infarct'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 21:28:14
User entered '5'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:16
User entered 'mg (mg)'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:22
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:24
User entered 'twice daily (BID)'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:19
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:27
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:29
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:30
User entered '15 Dec 2020'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:32
User entered '0'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:33
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:35
User entered empty.	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:28:36
User entered 'No (N)'	Mary Sergalis (b) (4)	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Dec 2020 14:06:40

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:26:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:44:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:44:55
Data point term sent to Coder	System	23 Jan 2021 16:45:00
User entered 'Heparin Sodium'	Mary Sergalis (b) (4) (b) (4) (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	29 Apr 2021 13:21:01
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 1). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 04:30:18
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 1). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	28 Apr 2021 20:20:33
DataPoint Un-verified.	Peter Jacob (b) (4) (b) (4)	28 Apr 2021 20:20:15
Signature has been broken.	Peter Jacob (b) (4) (b) (4)	28 Apr 2021 20:20:15
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	28 Apr 2021 20:20:15
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 1). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:01:25
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:26:53
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:26:55
User entered 'Myocardial Infarction'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:26:56
User entered '3500'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider: Units). Please update the unit as appropriate or provide explanation for alternate unit.	(b) (4)	08 Mar 2021 14:13:53
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider: Units). Please update the unit as appropriate or provide explanation for alternate unit.	(b) (4), (b) (6)	05 Mar 2021 15:27:22
' answered with 'Data updated.' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:27:12
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 15:27:12
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 15:27:12
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider: Units). Please update the unit as appropriate or provide explanation for alternate unit.	(b) (4), (b) (6)	05 Mar 2021 03:50:02
' (Site from DM).		
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4)	02 Feb 2021 21:26:57
User entered 'ug (ug)'	(b) (4), (b) (6)	
	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User closed query ' Per CDM-If dose unit is Other, specify is recorded as 'UNITS'. Kindly consider to verify and consider to update correct data else please clarify.Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:00:37
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
Query ' Per CDM-If dose unit is Other, specify is recorded as 'UNITS'. Kindly consider to verify and consider to update correct data else please clarify.Thank you.' answered with 'Data correct as is.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:22:55
User opened query ' Per CDM-If dose unit is Other, specify is recorded as 'UNITS'. Kindly consider to verify and consider to update correct data else please clarify.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:09:15
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:27:12
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 15:27:12
User entered 'Units' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 15:27:12
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:26:59
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:00
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:01
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:02
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:05
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:07
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:08
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:09
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:12
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:27:13
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User entered empty.	System	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User entered empty.	System	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:29
User entered empty.	System	23 Jan 2021 16:44:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:56:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:56:52
Data point term sent to Coder	System	23 Jan 2021 16:47:01
User entered 'Nitroglycerin 2%'	Mary Sergalis (b) (4) 	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:09
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:11
User entered 'Atrial Fibrillation'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:14
User entered 'l'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:20
User entered 'Other (OTHER)'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:22
User entered 'Patch'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:24
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:26
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:30
User entered 'Transdermal (TRANSDERMAL)'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:32
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:33
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:36
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:38
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:39
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:41
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User entered empty.	System	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User entered empty.	System	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:36:57
User entered empty.	System	23 Jan 2021 16:46:14

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:29:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:25:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:25:53
Data point term sent to Coder	System	23 Jan 2021 16:48:03
User entered 'Diltiazem'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:01
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:04
User entered 'Atrial fibrillation'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:06
User entered '10'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:08
User entered 'mg (mg)'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:11
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:13
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:14
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:19
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:22
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:24
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:26
User entered '0'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:27
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:29
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:32:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:30:31
User entered 'No (N)'	Mary Sergalis (b) (4)	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User entered empty.	System	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User entered empty.	System	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:17:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 05:37:33
User entered empty.	System	23 Jan 2021 16:47:13

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:17:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:16
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:18:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	23 Jan 2021 16:49:16
User entered 'No (N)'	Peter Jacob (b) (4)	16 Nov 2020 22:21:55

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:38
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:49:54

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:38
User entered 'CAT Scan Thorax'	Mary Sergalis (b) (4)	23 Jan 2021 16:49:54

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:38
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	23 Jan 2021 16:49:54

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:38

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:38
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:49:54

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:17:38

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:38
User entered '13 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:50:19

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:17:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:38
User entered 'Electrocardiogram'	Mary Sergalis (b) (4)	23 Jan 2021 16:50:19

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:17:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:38
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	23 Jan 2021 16:50:19

US3372274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:17:38

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:31:38
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:50:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'USA-US056-2020-MRNA-1273-P301000010'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Mira'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Baron'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '2277 Palm beach Lakes Blvd'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'West Palm Beach'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '33409'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:25
User entered 'US'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 14:11:44
User entered '5'	System	01 Apr 2021 14:01:01
User entered '4'	System	23 Mar 2021 10:05:35
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
	(b) (4)	
User entered '3'	System	25 Jan 2021 17:58:45
User entered '2'	System	25 Jan 2021 16:33:30
User entered '1'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'USA-US056-2020-MRNA-1273-P301000010'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Mira'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Baron'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '2277 Palm beach Lakes Blvd'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'West Palm Beach'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '33409'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:25
User entered 'US'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 14:11:44
User entered '5'	System	01 Apr 2021 14:01:01
User entered '4'	System	23 Mar 2021 10:05:35
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
	(b) (4)	
User entered '3'	System	25 Jan 2021 17:58:45
User entered '2'	System	25 Jan 2021 16:33:30
User entered '1'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:17:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
User entered '15/Dec/2020 14:44'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:17:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:25
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'USA-US056-2020-MRNA-1273-P301000010'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Mira'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Baron'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '2277 Palm beach Lakes Blvd'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'West Palm Beach'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '33409'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:25
User entered 'US'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 14:11:44
User entered '5'	System	01 Apr 2021 14:01:01
User entered '4'	System	23 Mar 2021 10:05:35
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
	(b) (4)	
User entered '3'	System	25 Jan 2021 17:58:45
User entered '2'	System	25 Jan 2021 16:33:30
User entered '1'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:17:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
User entered '25/Jan/2021 11:33'	System	25 Jan 2021 16:33:30

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:17:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:33:35
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 16:33:30

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'USA-US056-2020-MRNA-1273-P301000010'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Mira'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Baron'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '2277 Palm beach Lakes Blvd'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'West Palm Beach'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '33409'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:25
User entered 'US'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 14:11:44
User entered '5'	System	01 Apr 2021 14:01:01
User entered '4'	System	23 Mar 2021 10:05:35
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
	(b) (4)	
User entered '3'	System	25 Jan 2021 17:58:45
User entered '2'	System	25 Jan 2021 16:33:30
User entered '1'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:17:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
User entered '25/Jan/2021 12:58'	System	25 Jan 2021 17:58:45

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:17:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:58:49
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 17:58:45

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'USA-US056-2020-MRNA-1273-P301000010'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Mira'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Baron'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '2277 Palm beach Lakes Blvd'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'West Palm Beach'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '33409'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:25
User entered 'US'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 14:11:44
User entered '5'	System	01 Apr 2021 14:01:01
User entered '4'	System	23 Mar 2021 10:05:35
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
	(b) (4)	
User entered '3'	System	25 Jan 2021 17:58:45
User entered '2'	System	25 Jan 2021 16:33:30
User entered '1'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:17:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 11:44:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered '23/Mar/2021 10:05'	(b) (4) System	23 Mar 2021 10:05:35

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:17:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 11:44:43
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 14:00:52
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:47:18
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 10:05:35

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'USA-US056-2020-MRNA-1273-P301000010'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Mira'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Baron'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '2277 Palm beach Lakes Blvd'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'West Palm Beach'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '33409'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:25
User entered 'US'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 14:11:44
User entered '5'	System	01 Apr 2021 14:01:01
User entered '4'	System	23 Mar 2021 10:05:35
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
	(b) (4)	
User entered '3'	System	25 Jan 2021 17:58:45
User entered '2'	System	25 Jan 2021 16:33:30
User entered '1'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:17:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 11:44:43
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 16:03:13
User entered '01/Apr/2021 10:01'	(b) (4) System	01 Apr 2021 14:01:01

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:17:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:09:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 11:44:43
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 16:03:13
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 14:01:01

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'USA-US056-2020-MRNA-1273-P301000010'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Yes (Y)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'No (N)'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Mira'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'Baron'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '2277 Palm beach Lakes Blvd'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered 'West Palm Beach'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:10
User entered '33409'	System	15 Dec 2020 19:42:31

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:05:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 19:44:25
User entered 'US'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 14:11:44
User entered '5'	System	01 Apr 2021 14:01:01
User entered '4'	System	23 Mar 2021 10:05:35
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:31
	(b) (4)	
User entered '3'	System	25 Jan 2021 17:58:45
User entered '2'	System	25 Jan 2021 16:33:30
User entered '1'	System	15 Dec 2020 19:44:19

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:17:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
User entered '22/Apr/2021 10:11'	(b) (4) System	22 Apr 2021 14:11:44

US3372274

Folder: SAE USA-US056-2020-MRNA-1273-P301000010

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:17:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:39:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:11:44