

US3522173 (Prod: Henry Ford Health System)

Generated By: (b) (6)

Generated On: 11 Jun 2021 14:59:34

All time stamps listed in this document are displayed in GMT

US3522173

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 15:35:45

Generated On: 11 Jun 2021 14:59:34

[Participant ID](#)

US3522173

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

US3522173

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 18 AUG 2020

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

Folder OID SCRN

US3522173

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female <input checked="" type="radio"/> Male <input 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

US3522173

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Date of Informed Consent (*dd MMM yyyy*) 18 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3522173

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Did the participant meet all eligibility criteria?

Yes

No

US3522173

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Were any significant conditions reported?

Yes

No

US3522173

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Condition	OBESITY BMI > 40
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522173

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:10 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 08:10
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	326.8 lb
BMI (<i>xxx.x</i>)	54.49607 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)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*) 18 AUG 2020

Is the participant of childbearing potential? Yes
No

If No, what is the reason? Surgically sterile
Post-menopausal
Partner medically sterile
Not reached age of Menarche
Other

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown True

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:35:51

Generated On: 11 Jun 2021 14:59:34

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:35:51

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 18 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 144260

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

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 (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:10 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 08:10
Temperature (<i>xxx.x</i>)	96.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

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 (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:17 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 10:17
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
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>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 09:45

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 18 AUG 2020

Collection time (*00:00-23:59*) 08:38 (24 HR)

Collection date and time (derived) 18 AUG 2020 08:38

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Collection date (<i>dd MMM yyyy</i>)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:41	18 AUG 2020 08:41
Nasopharyngeal Swab 2	No		

US3522173

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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 97.7 °F

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

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

PC Time Stamp 18 AUG 2020 10:18

PC Open Date & Time 18 AUG 2020 10:05

PC Close Date & Time 18 AUG 2020 12:35

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.3 °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 18 AUG 2020 21:24
PC Open Date & Time 18 AUG 2020 13:30
PC Close Date & Time 19 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 AUG 2020 12:48
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 AUG 2020 17:34
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 AUG 2020 15:25
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 AUG 2020 12:14
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 AUG 2020 21:28
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 AUG 2020 12:23
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

18 AUG 2020 10:07

PC Open Date & Time

18 AUG 2020 10:05

PC Close Date & Time

18 AUG 2020 12:35

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

18 AUG 2020 21:22

PC Open Date & Time

18 AUG 2020 13:30

PC Close Date & Time

19 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	19 AUG 2020 12:49
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

20 AUG 2020 12:18

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

21 AUG 2020 15:23

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

22 AUG 2020 12:12

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	23 AUG 2020 12:10
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

24 AUG 2020 12:07

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

No

Yes

PC Time stamp	18 AUG 2020 10:06
PC Open Date & Time	18 AUG 2020 10:05
PC Close Date & Time	18 AUG 2020 12:35

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

No

Yes

PC Time stamp	18 AUG 2020 21:21
PC Open Date & Time	18 AUG 2020 13:30
PC Close Date & Time	19 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

	Yes <input type="checkbox"/>
PC Time stamp	19 AUG 2020 13:22
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 12:18
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

	Yes <input type="checkbox"/>
PC Time stamp	21 AUG 2020 15:24
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

Yes

PC Time stamp	23 AUG 2020 12:10
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 12:07
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3522173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments PATIENT DID NOT ANSWER;
VOICEMAIL WAS LEFT- WILL
If Contact Not Made, please provide Comments CALL AGAIN LATER TODAY

US3522173

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (dd MMM yyyy) 1 SEP 2020

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

Comments NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK.

If Contact Not Made, please provide Comments

US3522173

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

If Contact Not Made, please provide Comments

US3522173

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 15 SEP 2020

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

Folder OID VISIT2

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

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 (<i>dd MMM yyyy</i>)	15 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:40 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 08:40
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

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 (<i>dd MMM yyyy</i>)	15 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:52 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:52
Temperature (<i>xxx.x</i>)	96.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3522173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

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) 15 SEP 2020

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

Treatment Date and Time (derived) 15 SEP 2020 10:10

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

US3522173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	15 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:00 (24 HR)
Collection date and time (derived)	15 SEP 2020 09:00

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Collection date (<i>dd MMM yyyy</i>)	15 SEP 2020		
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:05	15 SEP 2020 09:05
Nasopharyngeal Swab 2	No		

US3522173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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 15 SEP 2020 10:48

PC Open Date & Time 15 SEP 2020 10:30

PC Close Date & Time 15 SEP 2020 13:00

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.3 °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 15 SEP 2020 17:56
PC Open Date & Time 15 SEP 2020 13:55
PC Close Date & Time 16 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 SEP 2020 12:26
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp 17 SEP 2020 19:04

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.1 °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 18 SEP 2020 17:18

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 19 SEP 2020 12:00
PC Close Date & Time 20 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 20 SEP 2020 12:00
PC Close Date & Time 21 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 SEP 2020 10:21
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

15 SEP 2020 10:46

PC Open Date & Time

15 SEP 2020 10:30

PC Close Date & Time

15 SEP 2020 13:00

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

15 SEP 2020 17:58

PC Open Date & Time

15 SEP 2020 13:55

PC Close Date & Time

16 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

16 SEP 2020 12:25

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 SEP 2020 19:05

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

18 SEP 2020 17:18

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

22 SEP 2020 10:19

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

No

Yes

PC Time stamp	15 SEP 2020 10:47
PC Open Date & Time	15 SEP 2020 10:30
PC Close Date & Time	15 SEP 2020 13:00

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

No

Yes

PC Time stamp	15 SEP 2020 17:57
PC Open Date & Time	15 SEP 2020 13:55
PC Close Date & Time	16 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

	Yes <input type="checkbox"/>
PC Time stamp	16 SEP 2020 12:25
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 19:05
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 17:18
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

Yes

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

Yes

PC Time stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 10:20
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3522173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes No

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

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

Comments EDIARY REVIEWED, PATIENT
If Contact Not Made, please provide Comments COULD NOT COMPLETE DAYS
5/6 DUE TO BROKEN CELL
PHONE. NO NEW ILLNESS OR
HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

US3522173

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (dd MMM yyyy) 29 SEP 2020

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

Comments NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK

If Contact Not Made, please provide Comments

US3522173

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3522173

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:42 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 07:42
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3522173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	15 OCT 2020
Collection time (<i>00:00-23:59</i>)	08:12 (24 HR)
Collection date and time (derived)	15 OCT 2020 08:12

US3522173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:14:43

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 18 OCT 2020 06:38:43

Patient Cloud Open Date & Time 18 OCT 2020 00:01

Patient Cloud Close Date & Time 22 OCT 2020 23:59

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 11:19:12
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 01 NOV 2020 00:02:20

Patient Cloud Open Date & Time 01 NOV 2020 00:01

Patient Cloud Close Date & Time 05 NOV 2020 23:59

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 15 NOV 2020 00:39:08

Patient Cloud Open Date & Time 15 NOV 2020 00:01

Patient Cloud Close Date & Time 19 NOV 2020 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 20:41:59
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 08:11:21
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 03 DEC 2020 07:35:41

Patient Cloud Open Date & Time 03 DEC 2020 00:01

Patient Cloud Close Date & Time 07 DEC 2020 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 <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	10 DEC 2020 00:06:51
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 06:13:02
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 <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	24 DEC 2020 04:01:44
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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	31 DEC 2020 00:01:46
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 07:00:42
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 15 JAN 2021 19:09:20

Patient Cloud Open Date & Time 14 JAN 2021 00:01

Patient Cloud Close Date & Time 18 JAN 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 06:59:46
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 22:21:30
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 07:21:17
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 05:16:14
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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	18 FEB 2021 06:56:08
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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	25 FEB 2021 02:19:43
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 03:50:12
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 11 MAR 2021 03:54:07

Patient Cloud Open Date & Time 11 MAR 2021 00:01

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 <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	18 MAR 2021 00:22:01
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 00:14:59
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 04:36:35
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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	08 APR 2021 06:01:26
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 06:35:01
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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	22 APR 2021 03:55:29
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission 29 APR 2021 07:10:22

Patient Cloud Open Date & Time 29 APR 2021 00:01

Patient Cloud Close Date & Time 03 MAY 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 285

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#) 07 JUN 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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
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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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
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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 411

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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
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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#) 13 DEC 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#) 27 DEC 2021 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#) 28 FEB 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission	
Patient Cloud Open Date & Time	03 MAR 2022 00:01
Patient Cloud Close Date & Time	07 MAR 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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
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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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
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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 635

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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20 JUN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

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27 JUN 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

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04 JUL 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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11 JUL 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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18 JUL 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

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01 AUG 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 15 AUG 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

DAY 747

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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°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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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
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

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3522173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Jun 2021 14:59:34

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 05:57:21

US3522173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 NOV 2020

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

Comments LOWER R. STOMACH PAIN FOR
If Contact Not Made, please provide Comments 2 WEEKS. VISIT TO PCP
YESTERDAY, WILL BE
TREATED FOR POSSIBLE
PEPTIC ULCER WITH
OMPERAZOLE 40 MG A DAY IF
NOT RESOLVED WILL DO
FURTHER WORKUP.
OTHERWISE, NO OTHER AE
REPORTED

US3522173

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 DEC 2020

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

Comments SEE SOURCE.

If Contact Not Made, please provide Comments

US3522173

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 JAN 2021

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

Comments R. LOWER STOMACH PAIN
RESOLVED ON 20 NOV 2020,
If Contact Not Made, please provide Comments BUT ACID REFLUX IS STILL
ONGOING. THE OMEPRAZOLE
IS STILL ONGOING AND HAS
HELPED SOMEWHAT. NO
OTHER AE REPORTED, NO
COVID-19 EXPOSURES

US3522173

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes
No

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

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

Comments ACID REFLUX HAS BEEN
IMPROVING FOR THE PAST
SEVERAL WEEKS AND SHE'S
TAKING THE OMEPRAZOLE 20
MG AS NEEDED NOW (SINCE 26
JAN 2021). OTHERWISE, NO
OTHER ONGOING OR NEW AE
REPORTED

If Contact Not Made, please provide Comments

US3522173

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 15:17:51

Generated On: 11 Jun 2021 14:59:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 MAR 2021

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

Folder OID VISIT4

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:33:09

Generated On: 11 Jun 2021 14:59:34

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) _____

US3522173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 15:17:51

Generated On: 11 Jun 2021 14:59:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3522173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 15:17:51

Generated On: 11 Jun 2021 14:59:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 MAR 2021

Collection time (*00:00-23:59*) 07:38 (24 HR)

Collection date and time (derived) 12 MAR 2021 07:38

US3522173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 15:17:51

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (dd MMM yyyy) 14 APR 2021

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

Comments RECOVERING WELL FROM 16
If Contact Not Made, please provide Comments MAR 2021 SURGERY AND WILL
CONTINUE TO BE MONITORED,
FOLLOW-UP CT IN JUNE 2021;
WILL ADDRESS LEFT UPPER
THIGH NUMBNESS WITH PCP IN
UPCOMING APPOINTMENT 26
MAR 2021.

US3522173

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522173

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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 _____

US3522173

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3522173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Jun 2021 14:59:34

Generate Next COVID-19 Assessment

Yes

No

US3522173

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 FEB 2021

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

Folder OID UNBLND_DECIDE

US3522173

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:06:22

Generated On: 11 Jun 2021 14:59:34

Date of updated informed consent (*dd MMM yyyy*) 02 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes
No

Under what version of the Protocol was the Participant unblinded? Amendment 5
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 31 DEC 2020

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____

Continuing with mRNA-1273 _____

US3522173

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 02 FEB 2021

Collection time (*00:00-23:59*) 07:46 (24 HR)

Collection date and time (derived) 02 FEB 2021 07:46

US3522173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 02 FEB 2021

Collection time (*00:00 - 23:59*) 07:47

Collection Date and Time (derived) 02 FEB 2021 07:47

US3522173

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 15:35:50

Generated On: 11 Jun 2021 14:59:34

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 22:32:52

Generated On: 11 Jun 2021 14:59:34

AEID	
Adverse event	RIGHT LOWER STOMACH 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)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 NOV 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	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 22:32:52

Generated On: 11 Jun 2021 14:59:34

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

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

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 22:32:52

Generated On: 11 Jun 2021 14:59:34

HAS BEEN HAVING LOWER
RIGHT STOMACH PAIN FOR
TWO WEEKS. VISIT TO PCP
YESTERDAY (09 NOV 2020),
WILL BE TREATED FOR
POSSIBLE PEPTIC ULCER WITH
OMPERAZOLE 40 MG TWICE A
DAY (STARTED TODAY, 10 NOV
2020) AND WILL TAKE IT FOR 14
DAYS AS WELL AS A "BLAND
DIET". IF NOT RESOLVED WILL
CONTINUE WITH FURTHER
WORKUP

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)	

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Apr 2021 22:32:52

Generated On: 11 Jun 2021 14:59:34

AEID	
Adverse event	ACID REFLUX EXACERBATION
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)	14 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Apr 2021 22:32:52

Generated On: 11 Jun 2021 14:59:34

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

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

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Apr 2021 22:32:52

Generated On: 11 Jun 2021 14:59:34

PATIENT STATES HER "HEARTBURN HAS BECOME WORSE IN THE PAST MONTH OR SO" START DATE UNKNOWN. SHE WAS PRESCRIBED 20 MG OMEPRAZOLE DAILY. 13 JAN 2021 UPDATE: R. LOWER STOMACH PAIN RESOLVED ON 20 NOV 2020, BUT ACID REFLUX IS STILL ONGOING. THE OMEPRAZOLE 40 MG STARTED BY PCP ON 10 NOV 2020 IS STILL ONGOING AND HAS HELPED SOMEWHAT. AT THIS POINT THERE'S NO PLAN TO INVESTIGATE THIS FURTHER WITH A SPECIALIST. 11 FEB 2021 UPDATE: ACID REFLUX HAS BEEN IMPROVING FOR THE PAST SEVERAL WEEKS AND SHE'S TAKING THE OMEPRAZOLE 20 MG AS NEEDED NOW (SINCE 26 JAN 2021). 12-MAR-2021 UPDATE: PARTICIPANT STATES REFLUX IS NOW UNDER CONTROL WITH INCREASED MEDICATION

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)	

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Folder: Adverse Events

Form: Adverse Events (3)

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AEID USA-US131-2021-MRNA-1273-P30
1000008

Adverse event STAGE 1A MUCINOUS
BORDERLINE TUMOR OF THE
OVARY WITH
INTRAEPITHELIAL
CARCINOMA

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) 19 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 16 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 16 MAR 2021

Hospital Discharge Date (dd MMM yyyy) 18 MAR 2021

Admitted to ICU?

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Yes

No

Unknown

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related

Related

Not Applicable

Relationship to Study Procedure Not Related

Related

Not Applicable

Action taken with investigational product None

Dose Delayed

Investigational Product

Withdrawn

Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

Outcome Fatal

Not Recovered/Not Resolved

Recovered/Resolved

Recovered/Resolved with Sequelae

Recovering/Resolving

Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

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Folder: Adverse Events

Form: Adverse Events (3)

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SPOKE TO PARTICIPANT TODAY ABOUT PARTICIPANTS TRIP TO THE EMERGENCY ROOM YESTERDAY. SHE HAD SLIPPED AND FALLEN ON ICE 2 DAYS PRIOR TO THE VISIT (2/19/21). SHE HAD ABDOMINAL PAIN (DESCRIBED TO SITE, PER DOCTOR VISIT IT WAS PELVIC PAIN) AFTER THAT. IT WAS INITIALLY MILD, BUT INCREASED TO SEVERE WITH CERTAIN MOVEMENTS. PARTICIPANT HAS A HISTORY OF POLYCYSTIC OVARIAN DISEASE STATUS POST RIGHT OOPHERECTOMY. PARTICIPANT HAD LAB WORK AND CT SCAN. SHE WAS GIVEN MORPHINE 4 MG/ML INJECTION 4 MG (4 MG INTRAVENOUS GIVEN 2/21/21 0957), KETOROLAC (TORADOL) 15 MG/ML INJECTION 15 MG (15 MG INTRAVENOUS GIVEN 2/21/21 0957), ACETAMINOPHEN (TYLENOL) TABLET 975 MG (975 MG ORAL GIVEN 2/21/21 0957), IOPAMIDOL (ISOVUE-300) CONTRAST FOR DILUTION 1,000 ML (1,000 MLS ORAL GIVEN 2/21/21 1013). SHE WAS PRESCRIBED: HYDROCODONE-ACETAMINOPHEN (NORCO) 5-325 MG PER

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Folder: Adverse Events

Form: Adverse Events (3)

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TABLET TAKE 1 TABLET BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN: IBUPROFEN (MOTRIN) 600 MG TABLET ,TAKE 1 TABLET (600 MG TOTAL) BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN. HER LAB WORK APPEARED NORMAL. HOWEVER CT SCAN SHOWED A LARGE PELVIC MASS THAT IS BELIEVED TO REPRESENT CYSTIC OVARIAN NEOPLASM. THEY WERE UNABLE TO LOCATE THE ORIGIN OF MASS. PARTICIPANT TO SEE OBGYN ONCOLOGY FOR FOLLOW UP AND FURTHER ASSESSMENT OF MASS... 18 MAR 2021 UPDATE: ON 16 MAR 2021 UNDERWENT "EXPLORATION LAPAROTOMY, REMOVAL OF PELVIC MASS, LEFT URETEROLYSIS, TOTAL ABDOMINAL HYSTERECTOMY, RIGHT SALPINGECTOMY, RIGHT URETEROLYSIS, RIGHT OOPHOROPEXY" AND DISCHARGED 18 MAR 2021. RESECTED RETROPERITONEAL MASS (BENIGN CYTOLOGY). 24 MAR 2021 PATHOLOGY REVIEW WAS STAGE 1A MUCINOUS BORDERLINE TUMOR OF THE OVARY WITH

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Apr 2021 22:32:52

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INTRAEPITHELIAL
CARCINOMA WITH
RECOMMENDATION OF
SURVEILLANCE. FOLLOW UP
GYN-ONC APPOINTMENT
SCHEDULED FOR 28-JUN-2021...
14 APR 2021 UPDATE: DOING
WELL POST SURGERY AND
WILL CONTINUE TO BE
MONITORED (TUMOR BOARD
ON 24 MAR 2021
RECOMMENDED
SURVEILLANCE), WILL HAVE A
ABD/PELVIC CT IN JUNE 2021

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 14 Apr 2021 22:32:52

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AEID	
Adverse event	LEFT UPPER THIGH NUMBNESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

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

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 14 Apr 2021 22:32:52

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HAS A FOLLOW-UP WITH PCP
ON 26 APR 2021 WHEN SHE
WILL ADDRESS A NUMBNESS
IN LEFT UPPER THIGH SINCE
POST SURGERY 16 MAR 2021.
POST SURGERY SHE HAD
LOWER BACK PAIN AND LEFT
LEG PAIN, WHICH IMPROVED
SOMEWHAT BUT NOT
COMPLETELY GONE.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 15:35:50

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

Yes

No

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Name of Medication METFORMIN

Prophylaxis Yes
No

Indication PRE-DIABETIC

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Name of Medication VENTOLIN

Prophylaxis Yes
No

Indication MILD ASTHMA

Dose per administration UNKNOWN

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) _____

Start date completely unknown True

Ongoing? Yes No

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

Was this medication taken for solicited event? Yes No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802 803 804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Name of Medication OMEPRAZOLE

Prophylaxis Yes
No

Indication LOWER RIGHT STOMACH PAIN

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 20 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Name of Medication OMEPRAZOLE

Prophylaxis Yes
No

Indication ACID REFLUX

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) _____

Start date completely unknown True

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Name of Medication INFUENZA QUAD WITH PRESERVATIVE

Prophylaxis Yes
No

Indication PREVENTION OF INFLUENZA

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

	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) 09 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 09 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Name of Medication OMEPRAZOLE

Prophylaxis Yes
No

Indication ACID REFLUX

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____ 26 JAN 2021

Start date completely unknown _____ False

Ongoing? _____ Yes
No

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

Was this medication taken for solicited event? _____ Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802
803
804

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Name of Medication MORPHINE

Prophylaxis Yes
No

Indication PELVIC MASS

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 21 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 21 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

Name of Medication KETOROLAC

Prophylaxis Yes
No

Indication PELVIC PAIN RELATED TO
PELVIC MASS

Dose per administration 15

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

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 checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 21 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 21 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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Name of Medication TYLENOL

Prophylaxis Yes
No

Indication PAIN RELATED TO PELVIC
MASS

Dose per administration 975

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 22:32:53

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	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*) 21 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 21 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

Name of Medication IOPAMIDOL CONTRAST

Prophylaxis Yes
No

Indication CT SCAN RELATED TO PAIN
FROM PELVIC MASS

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2205

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

	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*) 21 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 21 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

Name of Medication HYDROCODONE-ACETAMINOP
HEN (NORCO)

Prophylaxis Yes
No

Indication PELVIC PAIN RELATED TO
PELVIC MASS BELIEVED TO BE
A CYSTIC OVARIAN NEOPLASM

Dose per administration 5-325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

AS NEEDED EVERY SIX HOURS

Route of administration Oral
Topical
Subcutaneous

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2205

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 21 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication PAIN RELATED TO PELVIC
MASS

Dose per administration 600

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

AS NEEDED EVERY SIX HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2205

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

	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*) _____ 21 FEB 2021

Start date completely unknown _____ False

Ongoing? _____ Yes

_____ No

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

Was this medication taken for solicited event? _____ Yes

_____ No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802

_____ 803

_____ 804

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

Name of Medication LOVENOX

Prophylaxis Yes
No

Indication POST SURGICAL DVT
PROPHYLAXIS

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

	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)	18 MAR 2021
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 15:17:51

Generated On: 11 Jun 2021 14:59:34

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Mar 2021 18:06:22

Generated On: 11 Jun 2021 14:59:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 FEB 2021	CT SCAN, ABDOMEN/PELVIS	Adverse Event	
21 FEB 2021	LAB WORK	Adverse Event	
16 MAR 2021	EXPLORATION LAPAROTOMY, REMOVAL OF PELVIC MASS, LEFT URETEROLYSIS, TOTAL ABDOMINAL HYSTERECTOMY, RIGHT SALPINGECTOMY, RIGHT URETEROLYSIS, RIGHT OOPHOROPEXY	Adverse Event	

US3522173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:59:34

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

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P30 1000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/FEB/2021 14:18
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

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/MAR/2021 09:07
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.	<input checked="" type="checkbox"/> True

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/MAR/2021 09:36
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

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/MAR/2021 08:52
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

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/MAR/2021 12:48
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

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	06/APR/2021 16:04
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

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	07/APR/2021 09:27
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

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Data signed: (b) (4) 14 Apr 2021 22:32:53

Generated On: 11 Jun 2021 14:59:34

SAEID	USA-US131-2021-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	14/APR/2021 14:20
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

US3522173 (Prod: Henry Ford Health System)

US3522173

Form: Participant Creation

Generated On: 11 Jun 2021 14:59:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:45
User entered 'US3522173'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 12:04:27

US3522173

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:04:57

US3522173

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 12:04:28

US3522173

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Clinic (Clinic)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:04:57

US3522173

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'SCRN'	System	18 Aug 2020 12:04:57

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered (b) (6) 1977'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 12:04:29

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered '42'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'YEARS'	System	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered '42'	System	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Female (F)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '1'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:59:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:12:44

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'Aug 2020'	System	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered '2020'	System	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Amendment 1 (1)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:07:45

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 12:04:28

US3522173

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:59:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered '1'	System	18 Aug 2020 12:08:05

US3522173

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:08:05

US3522173

Folder: Screening

Form: Medical History Summary

Generated On: 11 Jun 2021 14:59:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:17:41

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User coded data point as SOC: Reproductive system and breast disorders, HLG: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 12:19:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 12:19:27
Data point term sent to Coder	System	18 Aug 2020 12:18:50
User entered 'PCOS'	Yaman Ahmed (b) (4)	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '1'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	18 Aug 2020 12:18:23

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGTT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 12:19:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 12:19:27
Data point term sent to Coder	System	18 Aug 2020 12:18:51
User entered 'Mild Asthma'	Yaman Ahmed (b) (4)	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '1'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	18 Aug 2020 12:18:43

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
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)	31 Aug 2020 14:03:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 14:03:48
Data point term sent to Coder	System	31 Aug 2020 14:02:23
User entered 'Obesity BMI > 40'	Sharon Mathys (b) (4)	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered '1'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered '0'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	31 Aug 2020 14:02:07

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User closed query 'Per DM CLR: Please provide the associated procedure that led to being surgically sterile (eg, bilateral tubal ligation, hysterectomy, etc) and provide a stop date. Ensure to capture associated medical condition of this procedure if applicable. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 10:31:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Salpingo-oophorectomy, LLT: Salpingo-oophorectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 16:09:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 16:09:52
Data point term sent to Coder	System	05 Oct 2020 18:16:40
Query 'Per DM CLR: Please provide the associated procedure that led to being surgically sterile (eg, bilateral tubal ligation, hysterectomy, etc) and provide a stop date. Ensure to capture associated medical condition of this procedure if applicable. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:15:59
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 18:15:50
User entered 'SALPINGOOPHORECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:15:50
User opened query 'Per DM CLR: Please provide the associated procedure that led to being surgically sterile (eg, bilateral tubal ligation, hysterectomy, etc) and provide a stop date. Ensure to capture associated medical condition of this procedure if applicable. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:04:28

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Sterilisation, LLT: Sterilization - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:55:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:55:51
Data point term sent to Coder	System	08 Sep 2020 19:55:25
User entered 'Surgically Sterile'	Sharon Mathys (b) (4)	08 Sep 2020 19:54:39
	(b) (4)	

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered '1'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:15:50
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:15:50
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	08 Sep 2020 19:54:39

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetic - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:46:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:46:42
Data point term sent to Coder	System	29 Sep 2020 19:45:29
User entered 'PRE-DIABETIC'	Kristin Eis (b) (4)	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '1'	(b) (4) Kristin Eis (b) (4)	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4)	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) Kristin Eis (b) (4)	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Kristin Eis (b) (4)	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	29 Sep 2020 19:45:28

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 13:16:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 13:16:29
Data point term sent to Coder	System	29 Jan 2021 13:14:49
User entered 'ACID REFLUX'	(b) (4), (b) (6)	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	29 Jan 2021 13:14:18

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 12:10:44
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	18 Aug 2020 12:10:44
User entered '08:10' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	18 Aug 2020 12:10:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 12:10:32
User entered empty.	Yaman Ahmed (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered '18 Aug 2020 08:10'	System	18 Aug 2020 12:10:44
User entered empty.	System	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '65' in	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:10:32
DataPoint set to visible.	(b) (4) System	18 Aug 2020 12:08:05

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '326.8' lb	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:10:32
DataPoint set to visible.	(b) (4) System	18 Aug 2020 12:08:05

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
Amendment Manager: User entered '54.49607'	System	17 Sep 2020 00:01:22
User entered '54.5'	System	18 Aug 2020 12:10:32
DataPoint set to visible.	System	18 Aug 2020 12:08:05

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'kg/m2'	System	18 Aug 2020 12:10:32
DataPoint set to visible.	System	18 Aug 2020 12:08:05

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:22:36
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 13:52:07
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'done' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 13:52:03
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 06:40:28
User entered 'Oral (Oral)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'bpm'	System	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered missing code ND - Not Done.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'breaths/min'	System	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered missing code ND - Not Done.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'mmHg'	System	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'mmHg'	System	18 Aug 2020 12:10:32

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18

US3522173

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18

US3522173

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:21:51

US3522173

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 03:46:08
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	15 Sep 2020 12:37:24
User entered '18 Aug 2020'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:21:51

US3522173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:14:48

US3522173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:59:34

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:14:48

US3522173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:59:34

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User closed query 'Per CDM: "If No, what is the reason" is "Surgically sterile"; however the procedure is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical procedures in "Medical History" form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:53:13
Query 'Per CDM: "If No, what is the reason" is "Surgically sterile"; however the procedure is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical procedures in "Medical History" form. Thank you.' answered with 'added' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 19:54:46
User opened query 'Per CDM: "If No, what is the reason" is "Surgically sterile"; however the procedure is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical procedures in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:06:51
User entered 'Surgically sterile (SURGICALLY STERILE)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:14:48

US3522173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:59:34

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:14:48

US3522173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:59:34

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:14:48

US3522173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:59:34

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '1'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:14:48

US3522173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:59:34

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:14:48

US3522173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:59:34

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:14:48

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '1'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:59:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:13:50

US3522173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:20:26

US3522173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:20:26

US3522173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Clinic (Clinic)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:20:26

US3522173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'VISIT1'	System	18 Aug 2020 12:20:26

US3522173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 12:24:22

US3522173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:59:34

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:12:13
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:12:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 12:24:22
User entered '144260' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 12:24:22

US3522173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:59:34

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 12:24:22

US3522173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:59:34

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:21:18

US3522173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:59:34

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:21:18

US3522173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:21:18

US3522173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:59:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:21:18

US3522173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:59:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:21:18

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:59:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:59:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:59:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:59:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User accepted default value 'Pre-Dose (PREDOSE)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '08:10'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '18 Aug 2020 08:10'	System	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 05:18:48
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	17 Sep 2020 13:47:30
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:01:22
User entered '96.7' F	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Other (Other)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Temporal'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '75'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'bpm'	System	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '20'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'breaths/min'	System	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '140'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '82'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:59:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:59:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:27

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User accepted default value 'Post-Dose (POSTDOSE)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 15:18:25
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 14:20:25
User entered '10:17'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '18 Aug 2020 10:17'	System	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '97.7' F	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4)	18 Aug 2020 14:22:06
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:22:06
User entered 'Other (Other)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	18 Aug 2020 14:22:06
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4)	18 Aug 2020 14:21:21
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:20:25
User entered empty.	Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	Yaman Ahmed (b) (4)	18 Aug 2020 14:21:21
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25
	(b) (4)	

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '79'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'bpm'	System	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '20'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'breaths/min'	System	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '120'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '78'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	18 Aug 2020 14:20:25

US3522173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:35

US3522173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:27:35

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 13:44:54
	(b) (4)	

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '09:45'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '18 Aug 2020 09:45'	System	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'ONCE'	System	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 13:44:54

US3522173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:39:03

US3522173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:39:03

US3522173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '08:38'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:39:03

US3522173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '18 Aug 2020 08:38'	System	18 Aug 2020 12:39:03

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 14:59:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '18 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:59:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '08:41'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '18 Aug 2020 08:41'	System	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:59:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered empty.	System	18 Aug 2020 12:40:58

US3522173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 13:45:17

US3522173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '1'	System	18 Aug 2020 13:45:17

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:18:10', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5bd18e4d-2717-4ec5-9d91-6f2ed854c6b3'	System	18 Aug 2020 14:18:48
User entered 'Yes (Y)'	System	18 Aug 2020 14:18:48

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:18:31', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5bd18e4d-2717-4ec5-9d91-6f2ed854c6b3'	System	18 Aug 2020 14:18:48
User entered '97.7'	System	18 Aug 2020 14:18:48

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:18:36', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5bd18e4d-2717-4ec5-9d91-6f2ed854c6b3'	System	18 Aug 2020 14:18:48
User entered 'No (N)'	System	18 Aug 2020 14:18:48

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:18:40', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5bd18e4d-2717-4ec5-9d91-6f2ed854c6b3'	System	18 Aug 2020 14:18:48
User entered '18 Aug 2020 10:18'	System	18 Aug 2020 14:18:48

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Aug 2020 10:05'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Aug 2020 12:35'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:23:52', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'fb5c9f5d-df4d-43b0-a871-05dc0eb7e262'	System	19 Aug 2020 01:24:32
User entered 'Yes (Y)'	System	19 Aug 2020 01:24:32

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:24:12', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'fb5c9f5d-df4d-43b0-a871-05dc0eb7e262'	System	19 Aug 2020 01:24:32
User entered '97.3'	System	19 Aug 2020 01:24:32

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:24:20', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'fb5c9f5d-df4d-43b0-a871-05dc0eb7e262'	System	19 Aug 2020 01:24:32
User entered 'No (N)'	System	19 Aug 2020 01:24:32

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:24:26', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'fb5c9f5d-df4d-43b0-a871-05dc0eb7e262'	System	19 Aug 2020 01:24:32
User entered '18 Aug 2020 21:24'	System	19 Aug 2020 01:24:32

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Aug 2020 13:30'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 2'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:47:53', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c1f6024e-b94d-4d29-b00f-2666b27e946e'	System	19 Aug 2020 16:48:19
User entered 'Yes (Y)'	System	19 Aug 2020 16:48:19

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:48:03', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c1f6024e-b94d-4d29-b00f-2666b27e946e'	System	19 Aug 2020 16:48:19
User entered '97.3'	System	19 Aug 2020 16:48:19

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:48:07', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c1f6024e-b94d-4d29-b00f-2666b27e946e'	System	19 Aug 2020 16:48:19
User entered 'No (N)'	System	19 Aug 2020 16:48:19

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:48:12', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c1f6024e-b94d-4d29-b00f-2666b27e946e'	System	19 Aug 2020 16:48:19
User entered '19 Aug 2020 12:48'	System	19 Aug 2020 16:48:19

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 3'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T17:34:16', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4c172aed-e15a-4fbd-a781-1ee086172659'	System	20 Aug 2020 21:34:38
User entered 'Yes (Y)'	System	20 Aug 2020 21:34:38

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T17:34:24', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4c172aed-e15a-4fbd-a781-1ee086172659'	System	20 Aug 2020 21:34:38
User entered '97.3'	System	20 Aug 2020 21:34:38

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T17:34:28', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4c172aed-e15a-4fbd-a781-1ee086172659'	System	20 Aug 2020 21:34:38
User entered 'No (N)'	System	20 Aug 2020 21:34:38

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T17:34:31', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4c172aed-e15a-4fbd-a781-1ee086172659'	System	20 Aug 2020 21:34:38
User entered '20 Aug 2020 17:34'	System	20 Aug 2020 21:34:38

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 4'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:24:12', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2ae16b2b-e63a-43f1-a2cb-9a003fa33471'	System	21 Aug 2020 19:25:31
User entered 'Yes (Y)'	System	21 Aug 2020 19:25:31

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:25:18', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2ae16b2b-e63a-43f1-a2cb-9a003fa33471'	System	21 Aug 2020 19:25:31
User entered '97.1'	System	21 Aug 2020 19:25:31

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:25:21', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2ae16b2b-e63a-43f1-a2cb-9a003fa33471'	System	21 Aug 2020 19:25:31
User entered 'No (N)'	System	21 Aug 2020 19:25:31

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:25:24', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2ae16b2b-e63a-43f1-a2cb-9a003fa33471'	System	21 Aug 2020 19:25:31
User entered '21 Aug 2020 15:25'	System	21 Aug 2020 19:25:31

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 5'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:49', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '75183d5f-f411-49f9-8a40-bb1cb2e0b454'	System	22 Aug 2020 16:14:41
User entered 'Yes (Y)'	System	22 Aug 2020 16:14:41

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:14:29', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '75183d5f-f411-49f9-8a40-bb1cb2e0b454'	System	22 Aug 2020 16:14:41
User entered '97.3'	System	22 Aug 2020 16:14:41

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:14:31', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '75183d5f-f411-49f9-8a40-bb1cb2e0b454'	System	22 Aug 2020 16:14:41
User entered 'No (N)'	System	22 Aug 2020 16:14:41

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:14:33', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '75183d5f-f411-49f9-8a40-bb1cb2e0b454'	System	22 Aug 2020 16:14:41
User entered '22 Aug 2020 12:14'	System	22 Aug 2020 16:14:41

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 6'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T21:27:15', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b42f3b91-fe8c-4891-97aa-ff5ddedd4551'	System	24 Aug 2020 01:28:37
User entered 'Yes (Y)'	System	24 Aug 2020 01:28:37

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T21:27:48', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b42f3b91-fe8c-4891-97aa-ff5ddedd4551'	System	24 Aug 2020 01:28:37
User entered '97.3'	System	24 Aug 2020 01:28:37

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T21:27:51', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b42f3b91-fe8c-4891-97aa-ff5ddedd4551'	System	24 Aug 2020 01:28:37
User entered 'No (N)'	System	24 Aug 2020 01:28:37

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T21:28:02', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b42f3b91-fe8c-4891-97aa-ff5ddedd4551'	System	24 Aug 2020 01:28:37
User entered '23 Aug 2020 21:28'	System	24 Aug 2020 01:28:37

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 7'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:52', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'f75a763e-3f0e-4c13-aea2-73e409e27376'	System	24 Aug 2020 16:23:17
User entered 'Yes (Y)'	System	24 Aug 2020 16:23:17

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:23:02', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'f75a763e-3f0e-4c13-aea2-73e409e27376'	System	24 Aug 2020 16:23:17
User entered '96.9'	System	24 Aug 2020 16:23:17

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:23:05', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'f75a763e-3f0e-4c13-aea2-73e409e27376'	System	24 Aug 2020 16:23:17
User entered 'No (N)'	System	24 Aug 2020 16:23:17

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:23:10', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'f75a763e-3f0e-4c13-aea2-73e409e27376'	System	24 Aug 2020 16:23:17
User entered '24 Aug 2020 12:23'	System	24 Aug 2020 16:23:17

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:07:07', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7106fe3d-3f8b-4de0-921c-02124170a652'	System	18 Aug 2020 14:07:51
User entered 'None (1)'	System	18 Aug 2020 14:07:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:07:23', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7106fe3d-3f8b-4de0-921c-02124170a652'	System	18 Aug 2020 14:07:51
User entered 'No (N)'	System	18 Aug 2020 14:07:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:07:27', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7106fe3d-3f8b-4de0-921c-02124170a652'	System	18 Aug 2020 14:07:51
User entered 'No (N)'	System	18 Aug 2020 14:07:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:07:40', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7106fe3d-3f8b-4de0-921c-02124170a652'	System	18 Aug 2020 14:07:51
User entered 'None (1)'	System	18 Aug 2020 14:07:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:07:44', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7106fe3d-3f8b-4de0-921c-02124170a652'	System	18 Aug 2020 14:07:51
User entered '18 Aug 2020 10:07'	System	18 Aug 2020 14:07:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '18 Aug 2020 10:05'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '18 Aug 2020 12:35'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:22:24', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4981c590-2b4c-4b8c-9e43-f2d66726ff70'	System	19 Aug 2020 01:22:47
User entered 'None (1)'	System	19 Aug 2020 01:22:47

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:22:20', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4981c590-2b4c-4b8c-9e43-f2d66726ff70'	System	19 Aug 2020 01:22:47
User entered 'No (N)'	System	19 Aug 2020 01:22:47

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:22:17', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4981c590-2b4c-4b8c-9e43-f2d66726ff70'	System	19 Aug 2020 01:22:47
User entered 'No (N)'	System	19 Aug 2020 01:22:47

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:22:32', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4981c590-2b4c-4b8c-9e43-f2d66726ff70'	System	19 Aug 2020 01:22:47
User entered 'None (1)'	System	19 Aug 2020 01:22:47

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:22:39', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4981c590-2b4c-4b8c-9e43-f2d66726ff70'	System	19 Aug 2020 01:22:47
User entered '18 Aug 2020 21:22'	System	19 Aug 2020 01:22:47

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '18 Aug 2020 13:30'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 2'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:48:41', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7961484f-898a-4563-842e-eda46b094def'	System	19 Aug 2020 16:49:07
User entered 'None (1)'	System	19 Aug 2020 16:49:07

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:48:48', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7961484f-898a-4563-842e-eda46b094def'	System	19 Aug 2020 16:49:07
User entered 'No (N)'	System	19 Aug 2020 16:49:07

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:48:52', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7961484f-898a-4563-842e-eda46b094def'	System	19 Aug 2020 16:49:07
User entered 'No (N)'	System	19 Aug 2020 16:49:07

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:48:57', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7961484f-898a-4563-842e-eda46b094def'	System	19 Aug 2020 16:49:07
User entered 'None (1)'	System	19 Aug 2020 16:49:07

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:49:01', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7961484f-898a-4563-842e-eda46b094def'	System	19 Aug 2020 16:49:07
User entered '19 Aug 2020 12:49'	System	19 Aug 2020 16:49:07

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
	[REDACTED]	
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 3'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:31', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '604ba9b5-f8df-4d1a-b161-98ff30a8ccfd'	System	20 Aug 2020 16:18:51
User entered 'None (1)'	System	20 Aug 2020 16:18:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:35', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '604ba9b5-f8df-4d1a-b161-98ff30a8ccfd'	System	20 Aug 2020 16:18:51
User entered 'No (N)'	System	20 Aug 2020 16:18:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:38', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '604ba9b5-f8df-4d1a-b161-98ff30a8ccfd'	System	20 Aug 2020 16:18:51
User entered 'No (N)'	System	20 Aug 2020 16:18:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:41', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '604ba9b5-f8df-4d1a-b161-98ff30a8ccfd'	System	20 Aug 2020 16:18:51
User entered 'None (1)'	System	20 Aug 2020 16:18:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:45', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '604ba9b5-f8df-4d1a-b161-98ff30a8ccfd'	System	20 Aug 2020 16:18:51
User entered '20 Aug 2020 12:18'	System	20 Aug 2020 16:18:51

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 4'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:36', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'caea897d-6b1e-46a4-8e69-989595fc827d'	System	21 Aug 2020 19:24:08
User entered 'None (1)'	System	21 Aug 2020 19:24:08

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:39', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'caea897d-6b1e-46a4-8e69-989595fc827d'	System	21 Aug 2020 19:24:08
User entered 'No (N)'	System	21 Aug 2020 19:24:08

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:41', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'caea897d-6b1e-46a4-8e69-989595fc827d'	System	21 Aug 2020 19:24:08
User entered 'No (N)'	System	21 Aug 2020 19:24:08

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:43', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'caea897d-6b1e-46a4-8e69-989595fc827d'	System	21 Aug 2020 19:24:08
User entered 'None (1)'	System	21 Aug 2020 19:24:08

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:46', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'caea897d-6b1e-46a4-8e69-989595fc827d'	System	21 Aug 2020 19:24:08
User entered '21 Aug 2020 15:23'	System	21 Aug 2020 19:24:08

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 5'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:28', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e9ca9119-f6f3-411e-9b11-e006c5d51ca6'	System	22 Aug 2020 16:12:48
User entered 'None (1)'	System	22 Aug 2020 16:12:48

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:33', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e9ca9119-f6f3-411e-9b11-e006c5d51ca6'	System	22 Aug 2020 16:12:48
User entered 'No (N)'	System	22 Aug 2020 16:12:48

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:34', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e9ca9119-f6f3-411e-9b11-e006c5d51ca6'	System	22 Aug 2020 16:12:48
User entered 'No (N)'	System	22 Aug 2020 16:12:48

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:38', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e9ca9119-f6f3-411e-9b11-e006c5d51ca6'	System	22 Aug 2020 16:12:48
User entered 'None (1)'	System	22 Aug 2020 16:12:48

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:40', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e9ca9119-f6f3-411e-9b11-e006c5d51ca6'	System	22 Aug 2020 16:12:48
User entered '22 Aug 2020 12:12'	System	22 Aug 2020 16:12:48

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 6'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:10:11', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4b6b441c-2123-461a-8e11-78d92f50456c'	System	23 Aug 2020 16:10:36
User entered 'None (1)'	System	23 Aug 2020 16:10:36

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:10:16', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4b6b441c-2123-461a-8e11-78d92f50456c'	System	23 Aug 2020 16:10:36
User entered 'No (N)'	System	23 Aug 2020 16:10:36

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:10:18', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4b6b441c-2123-461a-8e11-78d92f50456c'	System	23 Aug 2020 16:10:36
User entered 'No (N)'	System	23 Aug 2020 16:10:36

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:10:23', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4b6b441c-2123-461a-8e11-78d92f50456c'	System	23 Aug 2020 16:10:36
User entered 'None (1)'	System	23 Aug 2020 16:10:36

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:10:28', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4b6b441c-2123-461a-8e11-78d92f50456c'	System	23 Aug 2020 16:10:36
User entered '23 Aug 2020 12:10'	System	23 Aug 2020 16:10:36

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 7'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:27', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '69a60345-ac37-429a-b66d-4193ac650d2d'	System	24 Aug 2020 16:07:54
User entered 'None (1)'	System	24 Aug 2020 16:07:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:30', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '69a60345-ac37-429a-b66d-4193ac650d2d'	System	24 Aug 2020 16:07:54
User entered 'No (N)'	System	24 Aug 2020 16:07:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:33', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '69a60345-ac37-429a-b66d-4193ac650d2d'	System	24 Aug 2020 16:07:54
User entered 'No (N)'	System	24 Aug 2020 16:07:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:39', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '69a60345-ac37-429a-b66d-4193ac650d2d'	System	24 Aug 2020 16:07:54
User entered 'None (1)'	System	24 Aug 2020 16:07:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:44', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '69a60345-ac37-429a-b66d-4193ac650d2d'	System	24 Aug 2020 16:07:54
User entered '24 Aug 2020 12:07'	System	24 Aug 2020 16:07:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:06:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5fd79d79-2ced-42aa-be43-53fd052940f2'	System	18 Aug 2020 14:07:05
User entered 'None (0)'	System	18 Aug 2020 14:07:05

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:06:08', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5fd79d79-2ced-42aa-be43-53fd052940f2'	System	18 Aug 2020 14:07:05
User entered 'None (0)'	System	18 Aug 2020 14:07:05

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:06:14', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5fd79d79-2ced-42aa-be43-53fd052940f2'	System	18 Aug 2020 14:07:05
User entered 'None (0)'	System	18 Aug 2020 14:07:05

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:06:20', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5fd79d79-2ced-42aa-be43-53fd052940f2'	System	18 Aug 2020 14:07:05
User entered 'None (0)'	System	18 Aug 2020 14:07:05

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:06:33', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5fd79d79-2ced-42aa-be43-53fd052940f2'	System	18 Aug 2020 14:07:05
User entered 'None (0)'	System	18 Aug 2020 14:07:05

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:06:41', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5fd79d79-2ced-42aa-be43-53fd052940f2'	System	18 Aug 2020 14:07:05
User entered 'None (0)'	System	18 Aug 2020 14:07:05

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:06:49', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5fd79d79-2ced-42aa-be43-53fd052940f2'	System	18 Aug 2020 14:07:05
User entered 'No (N)'	System	18 Aug 2020 14:07:05

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T10:06:57', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5fd79d79-2ced-42aa-be43-53fd052940f2'	System	18 Aug 2020 14:07:05
User entered '18 Aug 2020 10:06'	System	18 Aug 2020 14:07:05

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '18 Aug 2020 10:05'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '18 Aug 2020 12:35'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:21:15', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c4d4fc6d-bf7d-4606-b6f2-1886a73a731d'	System	19 Aug 2020 01:21:58
User entered 'None (0)'	System	19 Aug 2020 01:21:58

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:21:21', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c4d4fc6d-bf7d-4606-b6f2-1886a73a731d'	System	19 Aug 2020 01:21:58
User entered 'None (0)'	System	19 Aug 2020 01:21:58

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:21:28', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c4d4fc6d-bf7d-4606-b6f2-1886a73a731d'	System	19 Aug 2020 01:21:58
User entered 'None (0)'	System	19 Aug 2020 01:21:58

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:21:33', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c4d4fc6d-bf7d-4606-b6f2-1886a73a731d'	System	19 Aug 2020 01:21:58
User entered 'None (0)'	System	19 Aug 2020 01:21:58

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:21:37', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c4d4fc6d-bf7d-4606-b6f2-1886a73a731d'	System	19 Aug 2020 01:21:58
User entered 'None (0)'	System	19 Aug 2020 01:21:58

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:21:42', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c4d4fc6d-bf7d-4606-b6f2-1886a73a731d'	System	19 Aug 2020 01:21:58
User entered 'None (0)'	System	19 Aug 2020 01:21:58

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:21:49', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c4d4fc6d-bf7d-4606-b6f2-1886a73a731d'	System	19 Aug 2020 01:21:58
User entered 'No (N)'	System	19 Aug 2020 01:21:58

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-18T21:21:52', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c4d4fc6d-bf7d-4606-b6f2-1886a73a731d'	System	19 Aug 2020 01:21:58
User entered '18 Aug 2020 21:21'	System	19 Aug 2020 01:21:58

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '18 Aug 2020 13:30'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 2'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:26:01', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '8593f4f1-aa13-4ea9-af63-bc345b82feb8'	System	19 Aug 2020 17:22:34
User entered 'None (0)'	System	19 Aug 2020 17:22:34

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:26:04', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '8593f4f1-aa13-4ea9-af63-bc345b82feb8'	System	19 Aug 2020 17:22:34
User entered 'None (0)'	System	19 Aug 2020 17:22:34

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:26:10', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '8593f4f1-aa13-4ea9-af63-bc345b82feb8'	System	19 Aug 2020 17:22:34
User entered 'None (0)'	System	19 Aug 2020 17:22:34

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:26:16', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '8593f4f1-aa13-4ea9-af63-bc345b82feb8'	System	19 Aug 2020 17:22:34
User entered 'None (0)'	System	19 Aug 2020 17:22:34

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:26:18', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '8593f4f1-aa13-4ea9-af63-bc345b82feb8'	System	19 Aug 2020 17:22:34
User entered 'None (0)'	System	19 Aug 2020 17:22:34

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T12:26:22', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '8593f4f1-aa13-4ea9-af63-bc345b82feb8'	System	19 Aug 2020 17:22:34
User entered 'None (0)'	System	19 Aug 2020 17:22:34

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T13:22:21', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '8593f4f1-aa13-4ea9-af63-bc345b82feb8'	System	19 Aug 2020 17:22:34
User entered 'No (N)'	System	19 Aug 2020 17:22:34

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-19T13:22:24', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '8593f4f1-aa13-4ea9-af63-bc345b82feb8'	System	19 Aug 2020 17:22:34
User entered '19 Aug 2020 13:22'	System	19 Aug 2020 17:22:34

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 3'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:17:56', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '269833c4-7332-439e-9aca-0bd5626b0b8a'	System	20 Aug 2020 16:18:31
User entered 'None (0)'	System	20 Aug 2020 16:18:31

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:17:59', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '269833c4-7332-439e-9aca-0bd5626b0b8a'	System	20 Aug 2020 16:18:31
User entered 'None (0)'	System	20 Aug 2020 16:18:31

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:06', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '269833c4-7332-439e-9aca-0bd5626b0b8a'	System	20 Aug 2020 16:18:31
User entered 'None (0)'	System	20 Aug 2020 16:18:31

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:10', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '269833c4-7332-439e-9aca-0bd5626b0b8a'	System	20 Aug 2020 16:18:31
User entered 'None (0)'	System	20 Aug 2020 16:18:31

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:13', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '269833c4-7332-439e-9aca-0bd5626b0b8a'	System	20 Aug 2020 16:18:31
User entered 'None (0)'	System	20 Aug 2020 16:18:31

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:16', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '269833c4-7332-439e-9aca-0bd5626b0b8a'	System	20 Aug 2020 16:18:31
User entered 'None (0)'	System	20 Aug 2020 16:18:31

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:20', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '269833c4-7332-439e-9aca-0bd5626b0b8a'	System	20 Aug 2020 16:18:31
User entered 'No (N)'	System	20 Aug 2020 16:18:31

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-20T12:18:24', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '269833c4-7332-439e-9aca-0bd5626b0b8a'	System	20 Aug 2020 16:18:31
User entered '20 Aug 2020 12:18'	System	20 Aug 2020 16:18:31

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 4'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:50', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3c715086-f651-414a-963b-61638ff81233'	System	21 Aug 2020 19:24:11
User entered 'None (0)'	System	21 Aug 2020 19:24:11

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:53', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3c715086-f651-414a-963b-61638ff81233'	System	21 Aug 2020 19:24:11
User entered 'None (0)'	System	21 Aug 2020 19:24:11

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:54', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3c715086-f651-414a-963b-61638ff81233'	System	21 Aug 2020 19:24:11
User entered 'None (0)'	System	21 Aug 2020 19:24:11

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:56', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3c715086-f651-414a-963b-61638ff81233'	System	21 Aug 2020 19:24:11
User entered 'None (0)'	System	21 Aug 2020 19:24:11

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:58', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3c715086-f651-414a-963b-61638ff81233'	System	21 Aug 2020 19:24:11
User entered 'None (0)'	System	21 Aug 2020 19:24:11

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:23:59', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3c715086-f651-414a-963b-61638ff81233'	System	21 Aug 2020 19:24:11
User entered 'None (0)'	System	21 Aug 2020 19:24:11

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:24:02', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3c715086-f651-414a-963b-61638ff81233'	System	21 Aug 2020 19:24:11
User entered 'No (N)'	System	21 Aug 2020 19:24:11

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-21T15:24:04', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3c715086-f651-414a-963b-61638ff81233'	System	21 Aug 2020 19:24:11
User entered '21 Aug 2020 15:24'	System	21 Aug 2020 19:24:11

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 5'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:02', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a62d78f4-56ad-41ef-8f74-c7b13333824e'	System	22 Aug 2020 16:12:33
User entered 'None (0)'	System	22 Aug 2020 16:12:33

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:05', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a62d78f4-56ad-41ef-8f74-c7b13333824e'	System	22 Aug 2020 16:12:33
User entered 'None (0)'	System	22 Aug 2020 16:12:33

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:07', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a62d78f4-56ad-41ef-8f74-c7b13333824e'	System	22 Aug 2020 16:12:33
User entered 'None (0)'	System	22 Aug 2020 16:12:33

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:08', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a62d78f4-56ad-41ef-8f74-c7b13333824e'	System	22 Aug 2020 16:12:33
User entered 'None (0)'	System	22 Aug 2020 16:12:33

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:10', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a62d78f4-56ad-41ef-8f74-c7b13333824e'	System	22 Aug 2020 16:12:33
User entered 'None (0)'	System	22 Aug 2020 16:12:33

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:13', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a62d78f4-56ad-41ef-8f74-c7b13333824e'	System	22 Aug 2020 16:12:33
User entered 'None (0)'	System	22 Aug 2020 16:12:33

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:21', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a62d78f4-56ad-41ef-8f74-c7b13333824e'	System	22 Aug 2020 16:12:33
User entered 'No (N)'	System	22 Aug 2020 16:12:33

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-22T12:12:24', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a62d78f4-56ad-41ef-8f74-c7b13333824e'	System	22 Aug 2020 16:12:33
User entered '22 Aug 2020 12:12'	System	22 Aug 2020 16:12:33

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 6'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:09:50', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e62fbed1-e39d-4a00-878c-56b7d7ac1760'	System	23 Aug 2020 16:10:14
User entered 'None (0)'	System	23 Aug 2020 16:10:14

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:09:53', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e62fbed1-e39d-4a00-878c-56b7d7ac1760'	System	23 Aug 2020 16:10:14
User entered 'None (0)'	System	23 Aug 2020 16:10:14

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:09:55', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e62fbed1-e39d-4a00-878c-56b7d7ac1760'	System	23 Aug 2020 16:10:14
User entered 'None (0)'	System	23 Aug 2020 16:10:14

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:09:57', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e62fbed1-e39d-4a00-878c-56b7d7ac1760'	System	23 Aug 2020 16:10:14
User entered 'None (0)'	System	23 Aug 2020 16:10:14

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:09:59', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e62fbed1-e39d-4a00-878c-56b7d7ac1760'	System	23 Aug 2020 16:10:14
User entered 'None (0)'	System	23 Aug 2020 16:10:14

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:10:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e62fbed1-e39d-4a00-878c-56b7d7ac1760'	System	23 Aug 2020 16:10:14
User entered 'None (0)'	System	23 Aug 2020 16:10:14

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:10:04', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e62fbed1-e39d-4a00-878c-56b7d7ac1760'	System	23 Aug 2020 16:10:14
User entered 'No (N)'	System	23 Aug 2020 16:10:14

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-23T12:10:06', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e62fbed1-e39d-4a00-878c-56b7d7ac1760'	System	23 Aug 2020 16:10:14
User entered '23 Aug 2020 12:10'	System	23 Aug 2020 16:10:14

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
	[REDACTED]	
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 7'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:05', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1713338f-b399-4492-861d-2ea6193e51b3'	System	24 Aug 2020 16:07:29
User entered 'None (0)'	System	24 Aug 2020 16:07:29

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:07', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1713338f-b399-4492-861d-2ea6193e51b3'	System	24 Aug 2020 16:07:29
User entered 'None (0)'	System	24 Aug 2020 16:07:29

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:09', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1713338f-b399-4492-861d-2ea6193e51b3'	System	24 Aug 2020 16:07:29
User entered 'None (0)'	System	24 Aug 2020 16:07:29

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:12', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1713338f-b399-4492-861d-2ea6193e51b3'	System	24 Aug 2020 16:07:29
User entered 'None (0)'	System	24 Aug 2020 16:07:29

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:13', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1713338f-b399-4492-861d-2ea6193e51b3'	System	24 Aug 2020 16:07:29
User entered 'None (0)'	System	24 Aug 2020 16:07:29

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:17', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1713338f-b399-4492-861d-2ea6193e51b3'	System	24 Aug 2020 16:07:29
User entered 'None (0)'	System	24 Aug 2020 16:07:29

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

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 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:20', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1713338f-b399-4492-861d-2ea6193e51b3'	System	24 Aug 2020 16:07:29
User entered 'No (N)'	System	24 Aug 2020 16:07:29

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-08-24T12:07:23', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1713338f-b399-4492-861d-2ea6193e51b3'	System	24 Aug 2020 16:07:29
User entered '24 Aug 2020 12:07'	System	24 Aug 2020 16:07:29

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 13:44:54

US3522173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:31
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4)	25 Aug 2020 13:21:38

US3522173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '25 Aug 2020'	(b) (4) Kristin Eis (b) (4)	25 Aug 2020 13:21:38

US3522173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Contact Not Made (CONTACT NOT MADE)'	Kristin Eis (b) (4)	25 Aug 2020 13:21:38

US3522173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'patient did not answer; voicemail was left- will call again later today'	Kristin Eis (b) (4)	25 Aug 2020 13:21:38

US3522173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4)	25 Aug 2020 13:21:44

US3522173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'I'	System	25 Aug 2020 13:21:44

US3522173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:32:05

US3522173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:32:05

US3522173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:32:05

US3522173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:32:05

US3522173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:35:59

US3522173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '1'	System	01 Sep 2020 14:35:59

US3522173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	08 Sep 2020 14:56:22

US3522173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '8 Sep 2020'	(b) (4) Yaman Ahmed (b) (4)	08 Sep 2020 14:56:22

US3522173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	08 Sep 2020 19:48:32
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Yaman Ahmed (b) (4)	08 Sep 2020 14:56:22

US3522173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	08 Sep 2020 19:48:32
User entered 'left a voicemail'	Yaman Ahmed (b) (4)	08 Sep 2020 14:56:22

US3522173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	08 Sep 2020 19:48:40

US3522173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '1'	System	08 Sep 2020 19:48:40

US3522173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:24

US3522173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Sep 2020'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:24

US3522173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Clinic (Clinic)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:24

US3522173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'VISIT2'	System	15 Sep 2020 12:37:24

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Sep 2020'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '08:40'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '15 Sep 2020 08:40'	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '97.9' F	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Other (Other)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'temporal'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '92'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'bpm'	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'breaths/min'	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '144'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '90'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 17:04:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 17:04:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:04:21
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 12:42:32
User entered empty.	Kristin Eis (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '10:52' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:06:10
User entered '11:03' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '15 Sep 2020 10:52'	System	15 Sep 2020 17:06:10
User entered '15 Sep 2020 11:03'	System	15 Sep 2020 17:04:21
User entered empty.	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '96.9' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:06:10
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Temporal' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '80' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:06:10
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'bpm'	System	15 Sep 2020 17:04:21
User entered empty.	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '18' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:06:10
User entered '12' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'breaths/min'	System	15 Sep 2020 17:04:21
User entered empty.	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '130' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:06:10
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	15 Sep 2020 17:04:21
User entered empty.	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '78' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:06:10
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:04:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	15 Sep 2020 17:04:21
User entered empty.	System	15 Sep 2020 12:42:32

US3522173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:33

US3522173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Sep 2020'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:33

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	15 Sep 2020 14:13:55
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	15 Sep 2020 14:13:55
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	15 Sep 2020 12:37:44
User entered 'Yes (Y)'	Kristin Eis (b) (4)	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:14:44
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered empty.	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Sep 2020'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '10:10' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:13:55
User entered empty.	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '15 Sep 2020 10:10'	System	15 Sep 2020 14:13:55
User entered empty.	System	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'ONCE'	System	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:59:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 12:37:44

US3522173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 13:13:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 13:13:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristin Eis (b) (4)	15 Sep 2020 13:13:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 12:42:53
User entered empty.	System	15 Sep 2020 12:42:53
	Kristin Eis (b) (4)	15 Sep 2020 12:42:53
	(b) (4)	

US3522173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 13:13:49
User entered empty.	Kristin Eis (b) (4)	15 Sep 2020 12:42:53
	(b) (4)	

US3522173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '09:00' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 13:13:49
User entered empty.	Kristin Eis (b) (4)	15 Sep 2020 12:42:53
	(b) (4)	

US3522173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '15 Sep 2020 09:00'	System	15 Sep 2020 13:13:49
User entered empty.	System	15 Sep 2020 12:42:53

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 14:59:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Sep 2020'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:59:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '09:05'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '15 Sep 2020 09:05'	System	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:59:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No (N)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered empty.	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered empty.	System	15 Sep 2020 13:14:04

US3522173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:37:49

US3522173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '1'	System	15 Sep 2020 12:37:49

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:48:14', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79cd0665-0cd1-4ecb-8240-0fd022be882c'	System	15 Sep 2020 14:48:48
User entered 'Yes (Y)'	System	15 Sep 2020 14:48:48

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:48:32', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79cd0665-0cd1-4ecb-8240-0fd022be882c'	System	15 Sep 2020 14:48:48
User entered '96.9'	System	15 Sep 2020 14:48:48

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:48:35', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79cd0665-0cd1-4ecb-8240-0fd022be882c'	System	15 Sep 2020 14:48:48
User entered 'No (N)'	System	15 Sep 2020 14:48:48

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:48:44', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79cd0665-0cd1-4ecb-8240-0fd022be882c'	System	15 Sep 2020 14:48:48
User entered '15 Sep 2020 10:48'	System	15 Sep 2020 14:48:48

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 10:30'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 13:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:56:40', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '47582109-63a2-48b5-9230-6c4a0a04a683'	System	15 Sep 2020 21:56:58
User entered 'Yes (Y)'	System	15 Sep 2020 21:56:58

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:56:46', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '47582109-63a2-48b5-9230-6c4a0a04a683'	System	15 Sep 2020 21:56:58
User entered '97.3'	System	15 Sep 2020 21:56:58

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:56:51', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '47582109-63a2-48b5-9230-6c4a0a04a683'	System	15 Sep 2020 21:56:58
User entered 'No (N)'	System	15 Sep 2020 21:56:58

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:56:55', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '47582109-63a2-48b5-9230-6c4a0a04a683'	System	15 Sep 2020 21:56:58
User entered '15 Sep 2020 17:56'	System	15 Sep 2020 21:56:58

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 13:55'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 2'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:26:17', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4f129cbc-568f-4c49-9976-917ed6396448'	System	16 Sep 2020 16:26:44
User entered 'Yes (Y)'	System	16 Sep 2020 16:26:44

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:26:22', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4f129cbc-568f-4c49-9976-917ed6396448'	System	16 Sep 2020 16:26:44
User entered '97.1'	System	16 Sep 2020 16:26:44

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:26:38', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4f129cbc-568f-4c49-9976-917ed6396448'	System	16 Sep 2020 16:26:44
User entered 'No (N)'	System	16 Sep 2020 16:26:44

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:26:40', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4f129cbc-568f-4c49-9976-917ed6396448'	System	16 Sep 2020 16:26:44
User entered '16 Sep 2020 12:26'	System	16 Sep 2020 16:26:44

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 3'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:04:09', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'fcfccd17-8daf-41b9-845e-9e6d12234904'	System	17 Sep 2020 23:04:41
User entered 'Yes (Y)'	System	17 Sep 2020 23:04:41

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:04:31', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'fcfccd17-8daf-41b9-845e-9e6d12234904'	System	17 Sep 2020 23:04:41
User entered '97.5'	System	17 Sep 2020 23:04:41

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:04:35', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'fcfccd17-8daf-41b9-845e-9e6d12234904'	System	17 Sep 2020 23:04:41
User entered 'No (N)'	System	17 Sep 2020 23:04:41

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:04:38', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'fcfccd17-8daf-41b9-845e-9e6d12234904'	System	17 Sep 2020 23:04:41
User entered '17 Sep 2020 19:04'	System	17 Sep 2020 23:04:41

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 4'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:02', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4390f76a-de71-4600-bd9a-f5cbb33278c6'	System	18 Sep 2020 21:18:26
User entered 'Yes (Y)'	System	18 Sep 2020 21:18:26

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:16', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4390f76a-de71-4600-bd9a-f5cbb33278c6'	System	18 Sep 2020 21:18:26
User entered '97.1'	System	18 Sep 2020 21:18:26

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:21', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4390f76a-de71-4600-bd9a-f5cbb33278c6'	System	18 Sep 2020 21:18:26
User entered 'No (N)'	System	18 Sep 2020 21:18:26

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:23', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4390f76a-de71-4600-bd9a-f5cbb33278c6'	System	18 Sep 2020 21:18:26
User entered '18 Sep 2020 17:18'	System	18 Sep 2020 21:18:26

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 5'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 6'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 7'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:20:28', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b406629a-4e91-48a2-a481-3ac7d5b29986'	System	22 Sep 2020 14:21:15
User entered 'Yes (Y)'	System	22 Sep 2020 14:21:15

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:20:56', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b406629a-4e91-48a2-a481-3ac7d5b29986'	System	22 Sep 2020 14:21:15
User entered '97.3'	System	22 Sep 2020 14:21:15

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:21:03', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b406629a-4e91-48a2-a481-3ac7d5b29986'	System	22 Sep 2020 14:21:15
User entered 'No (N)'	System	22 Sep 2020 14:21:15

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:21:11', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b406629a-4e91-48a2-a481-3ac7d5b29986'	System	22 Sep 2020 14:21:15
User entered '22 Sep 2020 10:21'	System	22 Sep 2020 14:21:15

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:46:23', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7244a4a6-6524-4a82-b1e6-5c320d8ec1e0'	System	15 Sep 2020 14:46:56
User entered 'None (1)'	System	15 Sep 2020 14:46:56

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:46:40', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7244a4a6-6524-4a82-b1e6-5c320d8ec1e0'	System	15 Sep 2020 14:46:56
User entered 'No (N)'	System	15 Sep 2020 14:46:56

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:46:46', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7244a4a6-6524-4a82-b1e6-5c320d8ec1e0'	System	15 Sep 2020 14:46:56
User entered 'No (N)'	System	15 Sep 2020 14:46:56

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:46:49', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7244a4a6-6524-4a82-b1e6-5c320d8ec1e0'	System	15 Sep 2020 14:46:56
User entered 'None (1)'	System	15 Sep 2020 14:46:56

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:46:53', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7244a4a6-6524-4a82-b1e6-5c320d8ec1e0'	System	15 Sep 2020 14:46:56
User entered '15 Sep 2020 10:46'	System	15 Sep 2020 14:46:56

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 10:30'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 13:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:58:04', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '647ec708-e6f9-4e39-b3fd-c7fcd3f3a448'	System	15 Sep 2020 21:58:45
User entered 'None (1)'	System	15 Sep 2020 21:58:45

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:58:09', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '647ec708-e6f9-4e39-b3fd-c7fcd3f3a448'	System	15 Sep 2020 21:58:45
User entered 'No (N)'	System	15 Sep 2020 21:58:45

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:58:13', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '647ec708-e6f9-4e39-b3fd-c7fcd3f3a448'	System	15 Sep 2020 21:58:45
User entered 'No (N)'	System	15 Sep 2020 21:58:45

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:58:18', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '647ec708-e6f9-4e39-b3fd-c7fcd3f3a448'	System	15 Sep 2020 21:58:45
User entered 'None (1)'	System	15 Sep 2020 21:58:45

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:58:22', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '647ec708-e6f9-4e39-b3fd-c7fcd3f3a448'	System	15 Sep 2020 21:58:45
User entered '15 Sep 2020 17:58'	System	15 Sep 2020 21:58:45

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 13:55'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 2'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:30', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '78daad56-9dc4-4d1a-89de-b32a7ccb8362'	System	16 Sep 2020 16:25:54
User entered 'None (1)'	System	16 Sep 2020 16:25:54

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:33', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '78daad56-9dc4-4d1a-89de-b32a7ccb8362'	System	16 Sep 2020 16:25:54
User entered 'No (N)'	System	16 Sep 2020 16:25:54

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:36', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '78daad56-9dc4-4d1a-89de-b32a7ccb8362'	System	16 Sep 2020 16:25:54
User entered 'No (N)'	System	16 Sep 2020 16:25:54

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:40', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '78daad56-9dc4-4d1a-89de-b32a7ccb8362'	System	16 Sep 2020 16:25:54
User entered 'None (1)'	System	16 Sep 2020 16:25:54

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:50', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '78daad56-9dc4-4d1a-89de-b32a7ccb8362'	System	16 Sep 2020 16:25:54
User entered '16 Sep 2020 12:25'	System	16 Sep 2020 16:25:54

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 3'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:04:58', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '294ce324-e29c-49f7-8148-1748b2f23037'	System	17 Sep 2020 23:05:29
User entered 'None (1)'	System	17 Sep 2020 23:05:29

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:06', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '294ce324-e29c-49f7-8148-1748b2f23037'	System	17 Sep 2020 23:05:29
User entered 'No (N)'	System	17 Sep 2020 23:05:29

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:08', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '294ce324-e29c-49f7-8148-1748b2f23037'	System	17 Sep 2020 23:05:29
User entered 'No (N)'	System	17 Sep 2020 23:05:29

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:12', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '294ce324-e29c-49f7-8148-1748b2f23037'	System	17 Sep 2020 23:05:29
User entered 'None (1)'	System	17 Sep 2020 23:05:29

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:26', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '294ce324-e29c-49f7-8148-1748b2f23037'	System	17 Sep 2020 23:05:29
User entered '17 Sep 2020 19:05'	System	17 Sep 2020 23:05:29

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 4'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:43', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '26f62d5e-5e02-4d61-914c-a88494eeb41f'	System	18 Sep 2020 21:18:57
User entered 'None (1)'	System	18 Sep 2020 21:18:57

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:46', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '26f62d5e-5e02-4d61-914c-a88494eeb41f'	System	18 Sep 2020 21:18:57
User entered 'No (N)'	System	18 Sep 2020 21:18:57

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:48', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '26f62d5e-5e02-4d61-914c-a88494eeb41f'	System	18 Sep 2020 21:18:57
User entered 'No (N)'	System	18 Sep 2020 21:18:57

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:50', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '26f62d5e-5e02-4d61-914c-a88494eeb41f'	System	18 Sep 2020 21:18:57
User entered 'None (1)'	System	18 Sep 2020 21:18:57

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:52', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '26f62d5e-5e02-4d61-914c-a88494eeb41f' User entered '18 Sep 2020 17:18'	System	18 Sep 2020 21:18:57
	System	18 Sep 2020 21:18:57

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 5'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 6'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 7'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:39', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4fb3a057-221c-4dfa-a56e-f5503e86bc5c'	System	22 Sep 2020 14:19:53
User entered 'None (1)'	System	22 Sep 2020 14:19:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:42', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4fb3a057-221c-4dfa-a56e-f5503e86bc5c'	System	22 Sep 2020 14:19:53
User entered 'No (N)'	System	22 Sep 2020 14:19:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:44', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4fb3a057-221c-4dfa-a56e-f5503e86bc5c'	System	22 Sep 2020 14:19:53
User entered 'No (N)'	System	22 Sep 2020 14:19:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:46', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4fb3a057-221c-4dfa-a56e-f5503e86bc5c'	System	22 Sep 2020 14:19:53
User entered 'None (1)'	System	22 Sep 2020 14:19:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:49', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '4fb3a057-221c-4dfa-a56e-f5503e86bc5c'	System	22 Sep 2020 14:19:53
User entered '22 Sep 2020 10:19'	System	22 Sep 2020 14:19:53

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:47:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6e532d54-712b-4932-8039-20bd517c72c9'	System	15 Sep 2020 14:47:36
User entered 'None (0)'	System	15 Sep 2020 14:47:36

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:47:03', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6e532d54-712b-4932-8039-20bd517c72c9'	System	15 Sep 2020 14:47:36
User entered 'None (0)'	System	15 Sep 2020 14:47:36

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:47:07', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6e532d54-712b-4932-8039-20bd517c72c9'	System	15 Sep 2020 14:47:36
User entered 'None (0)'	System	15 Sep 2020 14:47:36

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:47:11', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6e532d54-712b-4932-8039-20bd517c72c9'	System	15 Sep 2020 14:47:36
User entered 'None (0)'	System	15 Sep 2020 14:47:36

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:47:14', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6e532d54-712b-4932-8039-20bd517c72c9'	System	15 Sep 2020 14:47:36
User entered 'None (0)'	System	15 Sep 2020 14:47:36

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:47:17', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6e532d54-712b-4932-8039-20bd517c72c9'	System	15 Sep 2020 14:47:36
User entered 'None (0)'	System	15 Sep 2020 14:47:36

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:47:28', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6e532d54-712b-4932-8039-20bd517c72c9'	System	15 Sep 2020 14:47:36
User entered 'No (N)'	System	15 Sep 2020 14:47:36

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T10:47:31', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6e532d54-712b-4932-8039-20bd517c72c9'	System	15 Sep 2020 14:47:36
User entered '15 Sep 2020 10:47'	System	15 Sep 2020 14:47:36

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 10:30'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 13:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:57:01', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c96f52c7-6b3c-4d27-8abb-3761a5322beb'	System	15 Sep 2020 21:58:02
User entered 'No interference with activity (1)'	System	15 Sep 2020 21:58:02

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:57:12', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c96f52c7-6b3c-4d27-8abb-3761a5322beb'	System	15 Sep 2020 21:58:02
User entered 'None (0)'	System	15 Sep 2020 21:58:02

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:57:22', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c96f52c7-6b3c-4d27-8abb-3761a5322beb'	System	15 Sep 2020 21:58:02
User entered 'None (0)'	System	15 Sep 2020 21:58:02

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:57:26', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c96f52c7-6b3c-4d27-8abb-3761a5322beb'	System	15 Sep 2020 21:58:02
User entered 'None (0)'	System	15 Sep 2020 21:58:02

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:57:29', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c96f52c7-6b3c-4d27-8abb-3761a5322beb'	System	15 Sep 2020 21:58:02
User entered 'None (0)'	System	15 Sep 2020 21:58:02

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:57:36', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c96f52c7-6b3c-4d27-8abb-3761a5322beb'	System	15 Sep 2020 21:58:02
User entered 'None (0)'	System	15 Sep 2020 21:58:02

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:57:47', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c96f52c7-6b3c-4d27-8abb-3761a5322beb'	System	15 Sep 2020 21:58:02
User entered 'No (N)'	System	15 Sep 2020 21:58:02

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-15T17:57:56', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'c96f52c7-6b3c-4d27-8abb-3761a5322beb'	System	15 Sep 2020 21:58:02
User entered '15 Sep 2020 17:57'	System	15 Sep 2020 21:58:02

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '15 Sep 2020 13:55'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 2'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:24:47', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ce15596b-00cd-459c-9973-fbe612f87b69'	System	16 Sep 2020 16:25:28
User entered 'No interference with activity (1)'	System	16 Sep 2020 16:25:28

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:24:51', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ce15596b-00cd-459c-9973-fbe612f87b69'	System	16 Sep 2020 16:25:28
User entered 'No interference with activity (1)'	System	16 Sep 2020 16:25:28

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:24:56', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ce15596b-00cd-459c-9973-fbe612f87b69'	System	16 Sep 2020 16:25:28
User entered 'None (0)'	System	16 Sep 2020 16:25:28

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ce15596b-00cd-459c-9973-fbe612f87b69'	System	16 Sep 2020 16:25:28
User entered 'None (0)'	System	16 Sep 2020 16:25:28

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:03', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ce15596b-00cd-459c-9973-fbe612f87b69'	System	16 Sep 2020 16:25:28
User entered 'None (0)'	System	16 Sep 2020 16:25:28

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:06', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ce15596b-00cd-459c-9973-fbe612f87b69'	System	16 Sep 2020 16:25:28
User entered 'No interference with activity (1)'	System	16 Sep 2020 16:25:28

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:11', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ce15596b-00cd-459c-9973-fbe612f87b69'	System	16 Sep 2020 16:25:28
User entered 'No (N)'	System	16 Sep 2020 16:25:28

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-16T12:25:23', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ce15596b-00cd-459c-9973-fbe612f87b69'	System	16 Sep 2020 16:25:28
User entered '16 Sep 2020 12:25'	System	16 Sep 2020 16:25:28

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 3'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:38', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ad516a22-7294-47ae-8549-d543554ecfbf'	System	17 Sep 2020 23:05:54
User entered 'None (0)'	System	17 Sep 2020 23:05:54

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:39', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ad516a22-7294-47ae-8549-d543554ecfbf'	System	17 Sep 2020 23:05:54
User entered 'None (0)'	System	17 Sep 2020 23:05:54

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:41', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ad516a22-7294-47ae-8549-d543554ecfbf'	System	17 Sep 2020 23:05:54
User entered 'None (0)'	System	17 Sep 2020 23:05:54

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:42', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ad516a22-7294-47ae-8549-d543554ecfbf'	System	17 Sep 2020 23:05:54
User entered 'None (0)'	System	17 Sep 2020 23:05:54

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:44', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ad516a22-7294-47ae-8549-d543554ecfbf'	System	17 Sep 2020 23:05:54
User entered 'None (0)'	System	17 Sep 2020 23:05:54

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:45', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ad516a22-7294-47ae-8549-d543554ecfbf'	System	17 Sep 2020 23:05:54
User entered 'None (0)'	System	17 Sep 2020 23:05:54

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:47', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ad516a22-7294-47ae-8549-d543554ecfbf'	System	17 Sep 2020 23:05:54
User entered 'No (N)'	System	17 Sep 2020 23:05:54

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-17T19:05:49', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'ad516a22-7294-47ae-8549-d543554ecfbf'	System	17 Sep 2020 23:05:54
User entered '17 Sep 2020 19:05'	System	17 Sep 2020 23:05:54

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 4'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:27', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '725cf174-dae1-4460-9e6b-61fd0128e670'	System	18 Sep 2020 21:18:44
User entered 'None (0)'	System	18 Sep 2020 21:18:44

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:29', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '725cf174-dae1-4460-9e6b-61fd0128e670'	System	18 Sep 2020 21:18:44
User entered 'None (0)'	System	18 Sep 2020 21:18:44

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:31', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '725cf174-dae1-4460-9e6b-61fd0128e670'	System	18 Sep 2020 21:18:44
User entered 'None (0)'	System	18 Sep 2020 21:18:44

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:33', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '725cf174-dae1-4460-9e6b-61fd0128e670'	System	18 Sep 2020 21:18:44
User entered 'None (0)'	System	18 Sep 2020 21:18:44

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:34', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '725cf174-dae1-4460-9e6b-61fd0128e670'	System	18 Sep 2020 21:18:44
User entered 'None (0)'	System	18 Sep 2020 21:18:44

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:36', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '725cf174-dae1-4460-9e6b-61fd0128e670'	System	18 Sep 2020 21:18:44
User entered 'None (0)'	System	18 Sep 2020 21:18:44

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:38', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '725cf174-dae1-4460-9e6b-61fd0128e670'	System	18 Sep 2020 21:18:44
User entered 'No (N)'	System	18 Sep 2020 21:18:44

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fc29837a8516fc15)', Time: '2020-09-18T17:18:40', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '725cf174-dae1-4460-9e6b-61fd0128e670'	System	18 Sep 2020 21:18:44
User entered '18 Sep 2020 17:18'	System	18 Sep 2020 21:18:44

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 5'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 6'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	15 Sep 2020 14:13:55
User entered 'Day 7'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:53', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2a424064-ce8d-43fb-9bde-e31bfe92c361'	System	22 Sep 2020 14:20:07
User entered 'None (0)'	System	22 Sep 2020 14:20:07

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:55', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2a424064-ce8d-43fb-9bde-e31bfe92c361'	System	22 Sep 2020 14:20:07
User entered 'None (0)'	System	22 Sep 2020 14:20:07

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:57', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2a424064-ce8d-43fb-9bde-e31bfe92c361'	System	22 Sep 2020 14:20:07
User entered 'None (0)'	System	22 Sep 2020 14:20:07

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:19:58', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2a424064-ce8d-43fb-9bde-e31bfe92c361'	System	22 Sep 2020 14:20:07
User entered 'None (0)'	System	22 Sep 2020 14:20:07

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:20:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2a424064-ce8d-43fb-9bde-e31bfe92c361'	System	22 Sep 2020 14:20:07
User entered 'None (0)'	System	22 Sep 2020 14:20:07

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:20:01', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2a424064-ce8d-43fb-9bde-e31bfe92c361'	System	22 Sep 2020 14:20:07
User entered 'None (0)'	System	22 Sep 2020 14:20:07

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:20:03', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2a424064-ce8d-43fb-9bde-e31bfe92c361'	System	22 Sep 2020 14:20:07
User entered 'No (N)'	System	22 Sep 2020 14:20:07

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-09-22T10:20:05', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2a424064-ce8d-43fb-9bde-e31bfe92c361'	System	22 Sep 2020 14:20:07
User entered '22 Sep 2020 10:20'	System	22 Sep 2020 14:20:07

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:13:55

US3522173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:59:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:13:55

US3522173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	22 Sep 2020 14:26:35

US3522173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '22 Sep 2020'	(b) (4) Alandra White (b) (4)	22 Sep 2020 14:26:35

US3522173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Alandra White (b) (4)	22 Sep 2020 14:26:35

US3522173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'EDIARY REVIEWED, PATIENT COULD NOT COMPLETE DAYS 5/6 DUE TO BROKEN CELL PHONE. NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK' reason for change: Per Query Resolution	Alandra White (b) (4)	22 Sep 2020 14:26:48
User entered 'eDiary reviewed, patient could not complete days 5/6 due to broken cell phone.No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk' (non-conformant).	Alandra White (b) (4)	22 Sep 2020 14:26:35

US3522173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	22 Sep 2020 14:29:23

US3522173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '1'	System	22 Sep 2020 14:29:23

US3522173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	29 Sep 2020 20:44:24

US3522173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '29 Sep 2020'	(b) (4) Yaman Ahmed (b) (4)	29 Sep 2020 20:44:24

US3522173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	29 Sep 2020 20:44:24

US3522173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4) Yaman Ahmed (b) (4)	29 Sep 2020 20:44:24

US3522173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	29 Sep 2020 20:44:29

US3522173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'I'	System	29 Sep 2020 20:44:29

US3522173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:47:11

US3522173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:47:11

US3522173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:47:11

US3522173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:47:11

US3522173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:47:16

US3522173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'I'	System	06 Oct 2020 13:47:16

US3522173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	(b) (4) System	20 Oct 2020 14:06:32
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	15 Oct 2020 12:20:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 12:20:40

US3522173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:14:44
User entered '15 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	20 Oct 2020 14:06:32
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 12:20:40

US3522173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:20:40

US3522173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'VISIT3'	System	15 Oct 2020 12:20:40

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '07:42'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '15 Oct 2020 07:42'	System	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4)	15 Oct 2020 12:22:27
User entered 'temprral'	(b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '86'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'bpm'	System	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'breaths/min'	System	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '125'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '86'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered 'mmHg'	System	15 Oct 2020 12:22:08

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44

US3522173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44

US3522173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:20:46

US3522173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:20:46

US3522173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:20:55

US3522173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:20:55

US3522173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered '08:12'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:20:55

US3522173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '15 Oct 2020 08:12'	System	15 Oct 2020 12:20:55

US3522173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:20:59

US3522173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '1'	System	15 Oct 2020 12:20:59

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 64'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-10-18T06:37:49', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3f2fc0d9-0faf-43df-90b5-a948114a0cd1'	System	18 Oct 2020 10:38:39
User entered 'No (N)'	System	18 Oct 2020 10:38:39

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-10-18T06:38:08', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3f2fc0d9-0faf-43df-90b5-a948114a0cd1'	System	18 Oct 2020 10:38:39
User entered 'No (N)'	System	18 Oct 2020 10:38:39

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-10-18T06:38:43', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '3f2fc0d9-0faf-43df-90b5-a948114a0cd1' User entered '18 Oct 2020 06:38:43'	System	18 Oct 2020 10:38:39
	System	18 Oct 2020 10:38:39

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 71'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-10-29T11:19:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '396d6cf6-e1f9-4499-a30c-90cea02668a5'	System	29 Oct 2020 15:18:51
User entered 'No (N)'	System	29 Oct 2020 15:18:51

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-10-29T11:19:07', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '396d6cf6-e1f9-4499-a30c-90cea02668a5'	System	29 Oct 2020 15:18:51
User entered 'No (N)'	System	29 Oct 2020 15:18:51

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-10-29T11:19:12', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '396d6cf6-e1f9-4499-a30c-90cea02668a5' User entered '29 Oct 2020 11:19:12'	System	29 Oct 2020 15:18:51
	System	29 Oct 2020 15:18:51

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 78'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-11-01T00:02:01', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '66108639-74bf-4005-864d-7c3ccc4d18ce'	System	01 Nov 2020 04:01:59
User entered 'No (N)'	System	01 Nov 2020 04:01:59

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-11-01T00:02:17', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '66108639-74bf-4005-864d-7c3ccc4d18ce'	System	01 Nov 2020 04:01:59
User entered 'No (N)'	System	01 Nov 2020 04:01:59

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-11-01T00:02:20', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '66108639-74bf-4005-864d-7c3ccc4d18ce' User entered '01 Nov 2020 00:02:20'	System	01 Nov 2020 04:01:59
	System	01 Nov 2020 04:01:59

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered 'Day 92'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-11-15T00:38:50', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b505cd62-7a83-4870-b71f-07909553ac6f'	System	15 Nov 2020 05:38:47
User entered 'No (N)'	System	15 Nov 2020 05:38:47

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-11-15T00:39:04', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b505cd62-7a83-4870-b71f-07909553ac6f'	System	15 Nov 2020 05:38:47
User entered 'No (N)'	System	15 Nov 2020 05:38:47

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-11-15T00:39:08', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'b505cd62-7a83-4870-b71f-07909553ac6f' User entered '15 Nov 2020 00:39:08'	System	15 Nov 2020 05:38:47
	System	15 Nov 2020 05:38:47

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 13:44:54

US3522173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:01:53
Data entry locked.	System	18 Aug 2020 13:44:54
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 13:44:54

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2020-11-21T20:41:55', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '89f0b04e-aca6-4b7b-b03a-85cd290bdebf'	System	22 Nov 2020 01:41:40
User entered 'No (N)'	System	22 Nov 2020 01:41:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2020-11-21T20:41:57', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '89f0b04e-aca6-4b7b-b03a-85cd290bdebf'	System	22 Nov 2020 01:41:40
User entered 'No (N)'	System	22 Nov 2020 01:41:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-11-21T20:41:59', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '89f0b04e-aca6-4b7b-b03a-85cd290bdebf'	System	22 Nov 2020 01:41:40
User entered '21 Nov 2020 20:41:59'	System	22 Nov 2020 01:41:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2020-11-27T08:11:09', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '73d2bd19-409e-4811-94b2-5ad71002c16b'	System	27 Nov 2020 13:10:35
User entered 'No (N)'	System	27 Nov 2020 13:10:35

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2020-11-27T08:11:17', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '73d2bd19-409e-4811-94b2-5ad71002c16b'	System	27 Nov 2020 13:10:35
User entered 'No (N)'	System	27 Nov 2020 13:10:35

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-11-27T08:11:21', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '73d2bd19-409e-4811-94b2-5ad71002c16b'	System	27 Nov 2020 13:10:35
User entered '27 Nov 2020 08:11:21'	System	27 Nov 2020 13:10:35

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2020-12-03T07:35:26', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '571c8150-26ba-4825-92e1-9a7d5c6edd5b'	System	03 Dec 2020 12:34:51
User entered 'No (N)'	System	03 Dec 2020 12:34:51

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2020-12-03T07:35:38', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '571c8150-26ba-4825-92e1-9a7d5c6edd5b'	System	03 Dec 2020 12:34:51
User entered 'No (N)'	System	03 Dec 2020 12:34:51

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-12-03T07:35:41', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '571c8150-26ba-4825-92e1-9a7d5c6edd5b'	System	03 Dec 2020 12:34:51
User entered '03 Dec 2020 07:35:41'	System	03 Dec 2020 12:34:51

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2020-12-10T00:06:43', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '938ab7bd-a1fb-45b2-95ed-0611a5e95189'	System	10 Dec 2020 05:06:04
User entered 'No (N)'	System	10 Dec 2020 05:06:04

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2020-12-10T00:06:48', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '938ab7bd-a1fb-45b2-95ed-0611a5e95189'	System	10 Dec 2020 05:06:04
User entered 'No (N)'	System	10 Dec 2020 05:06:04

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-12-10T00:06:51', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '938ab7bd-a1fb-45b2-95ed-0611a5e95189'	System	10 Dec 2020 05:06:04
User entered '10 Dec 2020 00:06:51'	System	10 Dec 2020 05:06:04

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2020-12-17T06:12:55', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1d665a21-3004-42c8-8bee-749bc1bd7a8f'	System	17 Dec 2020 11:11:59
User entered 'No (N)'	System	17 Dec 2020 11:11:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2020-12-17T06:12:59', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1d665a21-3004-42c8-8bee-749bc1bd7a8f'	System	17 Dec 2020 11:11:59
User entered 'No (N)'	System	17 Dec 2020 11:11:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-12-17T06:13:02', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '1d665a21-3004-42c8-8bee-749bc1bd7a8f' User entered '17 Dec 2020 06:13:02'	System	17 Dec 2020 11:11:59
	System	17 Dec 2020 11:11:59

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2020-12-24T04:01:34', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'f5f0a0dc-ef8c-4757-8e0d-01e60fa7f420'	System	24 Dec 2020 09:00:34
User entered 'No (N)'	System	24 Dec 2020 09:00:34

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2020-12-24T04:01:41', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'f5f0a0dc-ef8c-4757-8e0d-01e60fa7f420'	System	24 Dec 2020 09:00:34
User entered 'No (N)'	System	24 Dec 2020 09:00:34

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-12-24T04:01:44', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'f5f0a0dc-ef8c-4757-8e0d-01e60fa7f420' User entered '24 Dec 2020 04:01:44'	System	24 Dec 2020 09:00:34
	System	24 Dec 2020 09:00:34

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2020-12-31T00:01:34', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '0ef5a75c-0024-4d74-b8c4-acbe689220fc'	System	31 Dec 2020 05:00:38
User entered 'No (N)'	System	31 Dec 2020 05:00:38

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2020-12-31T00:01:42', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '0ef5a75c-0024-4d74-b8c4-acbe689220fc'	System	31 Dec 2020 05:00:38
User entered 'No (N)'	System	31 Dec 2020 05:00:38

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2020-12-31T00:01:46', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '0ef5a75c-0024-4d74-b8c4-acbe689220fc' User entered '31 Dec 2020 00:01:46'	System	31 Dec 2020 05:00:38
	System	31 Dec 2020 05:00:38

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-01-07T07:00:36', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '0ef186e1-0573-4b64-bb4c-fe5a99e4d800'	System	07 Jan 2021 11:59:32
User entered 'No (N)'	System	07 Jan 2021 11:59:32

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-01-07T07:00:39', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '0ef186e1-0573-4b64-bb4c-fe5a99e4d800'	System	07 Jan 2021 11:59:32
User entered 'No (N)'	System	07 Jan 2021 11:59:32

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-01-07T07:00:42', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '0ef186e1-0573-4b64-bb4c-fe5a99e4d800'	System	07 Jan 2021 11:59:32
User entered '07 Jan 2021 07:00:42'	System	07 Jan 2021 11:59:32

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-01-15T19:09:12', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '97e1f9b9-883c-460d-a3da-45a250c735ec'	System	16 Jan 2021 00:07:53
User entered 'No (N)'	System	16 Jan 2021 00:07:53

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-01-15T19:09:18', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '97e1f9b9-883c-460d-a3da-45a250c735ec'	System	16 Jan 2021 00:07:53
User entered 'No (N)'	System	16 Jan 2021 00:07:53

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-01-15T19:09:20', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '97e1f9b9-883c-460d-a3da-45a250c735ec'	System	16 Jan 2021 00:07:53
User entered '15 Jan 2021 19:09:20'	System	16 Jan 2021 00:07:53

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 (8aa9339a31e01530)', Time: '2021-01-21T06:59:36', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6c899067-9985-4320-bfd0-1668596d55ea'	System	21 Jan 2021 11:58:17
User entered 'No (N)'	System	21 Jan 2021 11:58:17

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-01-21T06:59:43', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6c899067-9985-4320-bfd0-1668596d55ea'	System	21 Jan 2021 11:58:17
User entered 'No (N)'	System	21 Jan 2021 11:58:17

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-01-21T06:59:46', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '6c899067-9985-4320-bfd0-1668596d55ea'	System	21 Jan 2021 11:58:17
User entered '21 Jan 2021 06:59:46'	System	21 Jan 2021 11:58:17

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-01-29T22:21:24', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '648cd716-d571-44b5-966d-2bfa80714058'	System	30 Jan 2021 03:19:53
User entered 'No (N)'	System	30 Jan 2021 03:19:53

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-01-29T22:21:28', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '648cd716-d571-44b5-966d-2bfa80714058'	System	30 Jan 2021 03:19:53
User entered 'No (N)'	System	30 Jan 2021 03:19:53

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-01-29T22:21:30', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '648cd716-d571-44b5-966d-2bfa80714058'	System	30 Jan 2021 03:19:53
User entered '29 Jan 2021 22:21:30'	System	30 Jan 2021 03:19:53

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-02-04T07:21:10', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'd71ed5c8-6793-4b89-897c-f3d2cc655d2c'	System	04 Feb 2021 12:19:42
User entered 'No (N)'	System	04 Feb 2021 12:19:42

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-02-04T07:21:13', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'd71ed5c8-6793-4b89-897c-f3d2cc655d2c'	System	04 Feb 2021 12:19:42
User entered 'No (N)'	System	04 Feb 2021 12:19:42

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-02-04T07:21:17', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'd71ed5c8-6793-4b89-897c-f3d2cc655d2c'	System	04 Feb 2021 12:19:42
User entered '04 Feb 2021 07:21:17'	System	04 Feb 2021 12:19:42

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-02-11T05:16:07', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '438b887b-61d5-4a27-9bf7-5f02e55be2a2'	System	11 Feb 2021 10:14:37
User entered 'No (N)'	System	11 Feb 2021 10:14:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-02-11T05:16:10', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '438b887b-61d5-4a27-9bf7-5f02e55be2a2'	System	11 Feb 2021 10:14:37
User entered 'No (N)'	System	11 Feb 2021 10:14:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-02-11T05:16:14', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '438b887b-61d5-4a27-9bf7-5f02e55be2a2'	System	11 Feb 2021 10:14:37
User entered '11 Feb 2021 05:16:14'	System	11 Feb 2021 10:14:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 (8aa9339a31e01530)', Time: '2021-02-18T06:56:01', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a018a101-7ce2-41af-a54f-183864e0be93'	System	18 Feb 2021 11:54:29
User entered 'No (N)'	System	18 Feb 2021 11:54:29

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-02-18T06:56:03', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a018a101-7ce2-41af-a54f-183864e0be93'	System	18 Feb 2021 11:54:29
User entered 'No (N)'	System	18 Feb 2021 11:54:29

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-02-18T06:56:08', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'a018a101-7ce2-41af-a54f-183864e0be93'	System	18 Feb 2021 11:54:29
User entered '18 Feb 2021 06:56:08'	System	18 Feb 2021 11:54:29

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-02-25T02:19:35-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '86e2c144-4997-4a02-8542-6a17c60bdf69'	System	25 Feb 2021 07:18:05
User entered 'No (N)'	System	25 Feb 2021 07:18:05

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-02-25T02:19:38-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '86e2c144-4997-4a02-8542-6a17c60bdf69'	System	25 Feb 2021 07:18:05
User entered 'No (N)'	System	25 Feb 2021 07:18:05

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-02-25T02:19:43-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '86e2c144-4997-4a02-8542-6a17c60bdf69' User entered '25 Feb 2021 02:19:43'	System	25 Feb 2021 07:18:05
	System	25 Feb 2021 07:18:05

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-03-04T03:49:54-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7fca0ef2-c51b-4c99-9748-aafb65ccad22'	System	04 Mar 2021 08:48:37
User entered 'No (N)'	System	04 Mar 2021 08:48:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-03-04T03:50:09-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7fca0ef2-c51b-4c99-9748-aafb65ccad22'	System	04 Mar 2021 08:48:37
User entered 'No (N)'	System	04 Mar 2021 08:48:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-03-04T03:50:12-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7fca0ef2-c51b-4c99-9748-aafb65ccad22'	System	04 Mar 2021 08:48:37
User entered '04 Mar 2021 03:50:12'	System	04 Mar 2021 08:48:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-03-11T03:54:01-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '502ac6ba-91c2-4b85-8b93-0d2a33205516'	System	11 Mar 2021 08:52:32
User entered 'No (N)'	System	11 Mar 2021 08:52:32

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-03-11T03:54:04-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '502ac6ba-91c2-4b85-8b93-0d2a33205516'	System	11 Mar 2021 08:52:32
User entered 'No (N)'	System	11 Mar 2021 08:52:32

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-03-11T03:54:07-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '502ac6ba-91c2-4b85-8b93-0d2a33205516'	System	11 Mar 2021 08:52:32
User entered '11 Mar 2021 03:54:07'	System	11 Mar 2021 08:52:32

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-03-18T00:20:54-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79807eca-6f49-4d86-a2f8-fd96c6f2e4e5'	System	18 Mar 2021 04:19:54
User entered 'Yes (Y)'	System	18 Mar 2021 04:19:54

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-03-18T00:21:00-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79807eca-6f49-4d86-a2f8-fd96c6f2e4e5'	System	18 Mar 2021 04:19:54
User entered 'No (N)'	System	18 Mar 2021 04:19:54

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 (8aa9339a31e01530)', Time: '2021-03-18T00:21:08-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79807eca-6f49-4d86-a2f8-fd96c6f2e4e5'	System	18 Mar 2021 04:19:54
User entered 'No (N)'	System	18 Mar 2021 04:19:54

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 (8aa9339a31e01530)', Time: '2021-03-18T00:21:26-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79807eca-6f49-4d86-a2f8-fd96c6f2e4e5'	System	18 Mar 2021 04:19:54
User entered 'Yes (Y)'	System	18 Mar 2021 04:19:54

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Please 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 (8aa9339a31e01530)', Time: '2021-03-18T00:21:42-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79807eca-6f49-4d86-a2f8-fd96c6f2e4e5'	System	18 Mar 2021 04:19:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 04:19:54

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-03-18T00:22:01-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '79807eca-6f49-4d86-a2f8-fd96c6f2e4e5' User entered '18 Mar 2021 00:22:01'	System	18 Mar 2021 04:19:54
	System	18 Mar 2021 04:19:54

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-03-25T00:14:54-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2b7db395-43e6-4696-8589-2390d7a47a54'	System	25 Mar 2021 04:12:37
User entered 'No (N)'	System	25 Mar 2021 04:12:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-03-25T00:14:57-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2b7db395-43e6-4696-8589-2390d7a47a54'	System	25 Mar 2021 04:12:37
User entered 'No (N)'	System	25 Mar 2021 04:12:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-03-25T00:14:59-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '2b7db395-43e6-4696-8589-2390d7a47a54'	System	25 Mar 2021 04:12:37
User entered '25 Mar 2021 00:14:59'	System	25 Mar 2021 04:12:37

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-04-01T04:36:24-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5e736afc-9705-455e-8417-37863fb39edb'	System	01 Apr 2021 08:34:13
User entered 'No (N)'	System	01 Apr 2021 08:34:13

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-04-01T04:36:33-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5e736afc-9705-455e-8417-37863fb39edb'	System	01 Apr 2021 08:34:13
User entered 'No (N)'	System	01 Apr 2021 08:34:13

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-04-01T04:36:35-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '5e736afc-9705-455e-8417-37863fb39edb' User entered '01 Apr 2021 04:36:35'	System	01 Apr 2021 08:34:13
	System	01 Apr 2021 08:34:13

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-04-08T06:01:19-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'd5212321-1cf6-4d42-a175-75903c4281ae'	System	08 Apr 2021 09:59:05
User entered 'No (N)'	System	08 Apr 2021 09:59:05

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-04-08T06:01:23-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'd5212321-1cf6-4d42-a175-75903c4281ae'	System	08 Apr 2021 09:59:05
User entered 'No (N)'	System	08 Apr 2021 09:59:05

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-04-08T06:01:26-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'd5212321-1cf6-4d42-a175-75903c4281ae' User entered '08 Apr 2021 06:01:26'	System	08 Apr 2021 09:59:05
	System	08 Apr 2021 09:59:05

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-04-15T06:34:55-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7a530529-7795-43b4-9417-a2f87766a29d'	System	15 Apr 2021 10:32:39
User entered 'No (N)'	System	15 Apr 2021 10:32:39

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-04-15T06:34:57-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7a530529-7795-43b4-9417-a2f87766a29d'	System	15 Apr 2021 10:32:39
User entered 'No (N)'	System	15 Apr 2021 10:32:39

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-04-15T06:35:01-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7a530529-7795-43b4-9417-a2f87766a29d'	System	15 Apr 2021 10:32:39
User entered '15 Apr 2021 06:35:01'	System	15 Apr 2021 10:32:39

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

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 (8aa9339a31e01530)', Time: '2021-04-22T03:55:12-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e0175ce1-2009-49f9-a354-f00fd67acb6f'	System	22 Apr 2021 07:53:06
User entered 'No (N)'	System	22 Apr 2021 07:53:06

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-04-22T03:55:24-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e0175ce1-2009-49f9-a354-f00fd67acb6f'	System	22 Apr 2021 07:53:06
User entered 'No (N)'	System	22 Apr 2021 07:53:06

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-04-22T03:55:29-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'e0175ce1-2009-49f9-a354-f00fd67acb6f'	System	22 Apr 2021 07:53:06
User entered '22 Apr 2021 03:55:29'	System	22 Apr 2021 07:53:06

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[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 (8aa9339a31e01530)', Time: '2021-04-29T07:10:17-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7033a49d-99a9-4ad5-abb7-29cb1513fd1b'	System	29 Apr 2021 11:07:39
User entered 'No (N)'	System	29 Apr 2021 11:07:39

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

Have you been exposed to someone with 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 (8aa9339a31e01530)', Time: '2021-04-29T07:10:19-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7033a49d-99a9-4ad5-abb7-29cb1513fd1b'	System	29 Apr 2021 11:07:39
User entered 'No (N)'	System	29 Apr 2021 11:07:39

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-04-29T07:10:22-04:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: '7033a49d-99a9-4ad5-abb7-29cb1513fd1b' User entered '29 Apr 2021 07:10:22'	System	29 Apr 2021 11:07:39
	System	29 Apr 2021 11:07:39

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 09:54:40

US3522173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:59:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:54:40
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 09:54:40

US3522173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 14:59:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:00:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-02-28T05:57:09-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'cf08f0af-159d-4e85-b3f6-22507d776703'	System	28 Feb 2021 10:55:42
User entered 'No (N)'	System	28 Feb 2021 10:55:42

US3522173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 14:59:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:00:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8aa9339a31e01530)', Time: '2021-02-28T05:57:21-05:00', User OID: 'PatientReportedOutcome (US3522173)', ODM File OID: 'cf08f0af-159d-4e85-b3f6-22507d776703'	System	28 Feb 2021 10:55:42
User entered '28 Feb 2021 05:57:21'	System	28 Feb 2021 10:55:42

US3522173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:15:07

US3522173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:15:07

US3522173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:11:43
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	10 Nov 2020 15:15:07

US3522173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'LOWER R. STOMACH PAIN FOR 2 WEEKS. VISIT TO PCP YESTERDAY, WILL BE TREATED FOR POSSIBLE PEPTIC ULCER WITH OMPERAZOLE 40 MG A DAY IF NOT RESOLVED WILL do FURTHER WORKUP. OTHERWISE, NO OTHER AE REPORTED' reason for change: New Information	Yaman Ahmed (b) (4)	10 Nov 2020 19:14:39
User entered 'Has been having lower right stomach pain for two weeks. visit to PCP yesterday (09 Nov 2020), will be treated for possible peptic ulcer with Omperazole 40 mg twice a day (started today, 10 Nov 2020) and will take it for 14 days as well as a "bland diet". If not resolved will continue with further workup. Otherwise, no other AE reported' (non-conformant).	Yaman Ahmed (b) (4)	10 Nov 2020 19:12:22
User entered 'no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk' reason for change: New Information	Yaman Ahmed (b) (4)	10 Nov 2020 19:11:43
User entered 'call attempted; VM left with return contact information.'	(b) (4), (b) (6)	10 Nov 2020 15:15:07

US3522173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:14:44

US3522173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:33:44
User entered '1'	System	10 Nov 2020 19:14:44

US3522173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:34:34

US3522173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:34:34

US3522173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:34:34

US3522173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'sEE SOURCE.'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:34:34

US3522173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:34:39

US3522173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered '1'	System	14 Dec 2020 21:34:39

US3522173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	13 Jan 2021 20:21:36

US3522173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '13 Jan 2021'	(b) (4) Yaman Ahmed (b) (4)	13 Jan 2021 20:21:36

US3522173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	13 Jan 2021 20:21:36

US3522173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'R. LOWER STOMACH PAIN RESOLVED ON 20 NOV 2020, BUT ACID REFLUX IS STILL ONGOING. THE OMEPRAZOLE IS STILL ONGOING AND HAS HELPED SOMEWHAT. No other AE reported, no covid-19 exposures' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	13 Jan 2021 20:23:09
User entered 'R. LOWER STOMACH PAIN RESOLVED ON 20 NOV 2020, BUT ACID REFLUX IS STILL ONGOING. THE OMEPRAZOLE IS STILL ONGOING AND HAS HELPED SOMEWHAT.THERE'S NO PLAN TO INVESTIGATE THIS FURTHER WITH A SPECIALIST.' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	13 Jan 2021 20:22:22
User entered 'R. Lower stomach pain resolved on 20 Nov 2020, but acid reflux is still ongoing. The Omeprazole 40 mg started by PCP on 10 Nov 2020 is still ongoing and has helped somewhat. At this point there's no plan to investigate this further with a specialist.' (non-conformant).	Yaman Ahmed (b) (4)	13 Jan 2021 20:21:36

US3522173

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	13 Jan 2021 20:22:30

US3522173

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered '1'	System	13 Jan 2021 20:22:30

US3522173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:38:39

US3522173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '11 Feb 2021'	(b) (4) Yaman Ahmed (b) (4)	11 Feb 2021 17:38:39

US3522173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	11 Feb 2021 17:38:39

US3522173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Acid Reflux has been improving for the past several weeks and she's taking the omeprazole 20 mg as needed now (since 26 Jan 2021). Otherwise, no other ongoing or new AE reported'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:38:39

US3522173

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:38:44

US3522173

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered '1'	System	11 Feb 2021 17:38:44

US3522173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:16:36

US3522173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered '12 Mar 2021'	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:16:36

US3522173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Clinic (Clinic)'	(b) (4) Alandra White (b) (4)	12 Mar 2021 12:16:36
	(b) (4)	

US3522173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered 'VISIT4'	System	12 Mar 2021 12:16:36

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered empty.	System	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered empty.	System	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered empty.	System	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered empty.	System	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:33:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered empty.	System	31 Mar 2021 12:42:09

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29

US3522173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:59:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29

US3522173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:16:44

US3522173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:59:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '12 Mar 2021'	(b) (4) Alandra White (b) (4)	12 Mar 2021 12:16:44
	(b) (4)	

US3522173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:40:40

US3522173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '12 Mar 2021'	(b) (4) Alandra White (b) (4)	12 Mar 2021 12:40:40

US3522173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '07:38'	(b) (4) Alandra White (b) (4)	12 Mar 2021 12:40:40

US3522173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered '12 Mar 2021 07:38'	System	12 Mar 2021 12:40:40

US3522173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:16:52

US3522173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:07:29
User entered '1'	System	12 Mar 2021 12:16:52

US3522173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 14:19:47

US3522173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered '14 Apr 2021'	(b) (4) Yaman Ahmed (b) (4)	14 Apr 2021 14:19:47
	(b) (4)	

US3522173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4)	14 Apr 2021 15:12:17
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4)	14 Apr 2021 14:19:47
	(b) (4)	

US3522173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:59:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'recovering well from 16 Mar 2021 surgery and will continue to be monitored, follow-up CT in June 2021; will address left upper thigh numbness with PCP in upcoming appointment 26 Mar 2021.' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:12:17
User entered 'left a voicemail message'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 14:19:47

US3522173

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:12:30

US3522173

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:59:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 15:12:30

US3522173

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

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:25

US3522173

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

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:25

US3522173

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

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[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 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:25

US3522173

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

Form: Visit Date

Generated On: 11 Jun 2021 14:59:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 12:55:25

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:49

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) Sharon Mathys (b) (4)	16 Mar 2021 19:44:16
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:28:27

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:49

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Amendment 5 (Amendment 5)'	(b) (4) Sharon Mathys (b) (4)	16 Mar 2021 19:44:16
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:28:27

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 06:57:26
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'AMENDMENT 5 UNBLINDING' (Site from System).	(b) (4), (b) (6)	02 Feb 2021 12:55:57
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	02 Feb 2021 12:55:49
User entered '31 Dec 2020'	(b) (4), (b) (6)	02 Feb 2021 12:55:49

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:49

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:49

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:49

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:55:49

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	02 Feb 2021 12:55:49

US3522173

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

Form: Unblinding

Generated On: 11 Jun 2021 14:59:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered empty.	System	02 Feb 2021 12:55:49

US3522173

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:56:17

US3522173

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:56:17

US3522173

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '07:46'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:56:17

US3522173

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:59:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered '02 Feb 2021 07:46'	System	02 Feb 2021 12:56:17

US3522173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:59:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:56:35

US3522173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:59:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:56:35

US3522173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:59:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '07:47'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 12:56:35

US3522173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:59:34

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:18
User entered '02 Feb 2021 07:47'	System	02 Feb 2021 12:56:35

US3522173

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Jun 2021 14:59:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:16
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:14:56
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	15 Sep 2020 12:36:41

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Stomach pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	10 Nov 2020 23:40:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:40:46
Data point term sent to Coder	System	10 Nov 2020 19:17:12
User entered 'right lower stomach pain'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
	(b) (4)	
User entered '27 Oct 2020'	Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4)	13 Jan 2021 20:23:56
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
	(b) (4)	
User entered '20 Nov 2020' reason for change: New Information	Yaman Ahmed (b) (4)	13 Jan 2021 20:23:56
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'None (NONE)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'I'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	13 Jan 2021 20:23:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Has been having lower right stomach pain for two weeks. visit to PCP yesterday (09 Nov 2020), will be treated for possible peptic ulcer with Omperazole 40 mg twice a day (started today, 10 Nov 2020) and will take it for 14 days as well as a "bland diet". If not resolved will continue with further workup'	(b) (4)	
	Yaman Ahmed (b) (4)	10 Nov 2020 19:16:45
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:59:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:16:45

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User closed query 'Per DM CLR: Please confirm the AE term "ACID RELFUX WORSE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 08:07:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 13:48:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 13:48:18
Data point term sent to Coder	System	29 Jan 2021 13:13:48
Query 'Per DM CLR: Please confirm the AE term "ACID RELFUX WORSE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with 'added to baseline med history' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:13:43
Coding entries removed.	(b) (4), (b) (6)	29 Jan 2021 13:13:34
User entered 'ACID REFLUX EXACERBATION' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:13:34
User opened query 'Per DM CLR: Please confirm the AE term "ACID RELFUX WORSE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:34:04

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 11:14:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 11:14:12
Data point term sent to Coder	System	14 Dec 2020 21:37:43
User entered 'aCID RELFUX WORSE'	(b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is "VERIFIED". Is it verified as ONGOING or an END DATE is verified? Please review and clarify as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 03:13:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
Query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is "VERIFIED". Is it verified as ONGOING or an END DATE is verified? Please review and clarify as appropriate. ' answered with 'end date added' (Site from DM).	Alandra White (b) (4)	12 Mar 2021 13:33:05
User entered 'No (N)' reason for change: Data Entry Error	Alandra White (b) (4)	12 Mar 2021 13:32:23
User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is "VERIFIED". Is it verified as ONGOING or an END DATE is verified? Please review and clarify as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:49:51
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 08:07:52
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'verified' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:13:50
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:40:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	12 Mar 2021 13:32:23
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	12 Mar 2021 13:32:23
User entered '1 Mar 2021' reason for change: Data Entry Error	Alandra White (b) (4)	12 Mar 2021 13:32:23
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	12 Mar 2021 13:32:09
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 21:36:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	12 Mar 2021 13:32:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT STATES HER "HEARTBURN HAS BECOME WORSE IN THE PAST MONTH OR SO" START DATE UNKNOWN. SHE WAS PRESCRIBED 20 MG OMEPRAZOLE DAILY. 13 JAN 2021 UPDATE: R. LOWER STOMACH PAIN RESOLVED ON 20 NOV 2020, BUT ACID REFLUX IS STILL ONGOING. THE OMEPRAZOLE 40 MG STARTED BY PCP ON 10 NOV 2020 IS STILL ONGOING AND HAS HELPED SOMEWHAT. AT THIS POINT THERE'S NO PLAN TO INVESTIGATE THIS FURTHER WITH A SPECIALIST. 11 FEB 2021 UPDATE: ACID REFLUX HAS BEEN IMPROVING FOR THE PAST SEVERAL WEEKS AND SHE'S TAKING THE OMEPRAZOLE 20 MG AS NEEDED NOW (SINCE 26 JAN 2021). 12-MAR-2021 UPDATE: PARTICIPANT STATES REFLUX IS NOW UNDER CONTROL WITH INCREASED MEDICATION' (WR#5445128)	System	11 Jun 2021 14:45:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'PATIENT STATES HER "HEARTBURN HAS BECOME WORSE IN THE PAST MONTH OR SO" START DATE UNKNOWN. SHE WAS PRESCRIBED 20 MG OMEPRAZOLE DAILY. 13 JAN 2021 UPDATE: R. LOWER STOMACH PAIN RESOLVED ON 20 NOV 2020, BUT ACID REFLUX IS STILL ONGOING. THE OMEPRAZOLE 40 MG STARTED BY PCP ON 10 NOV 2020 IS STILL ONGOING AND HAS HELPED SOMEWHAT. AT THIS POINT THERE'S NO PLAN TO INVESTIGATE THIS FURTHER WITH A SPECIALIST. 11 FEB 2021 UPDATE: ACID REFLUX HAS BEEN IMPROVING FOR THE PAST SEVERAL WEEKS AND SHE'S TAKING THE OMEPRAZOLE 20 MG AS NEEDED NOW (SINCE 26 JAN 2021). 12-MAR-2021 update: participant states reflux is now under control with increased medication' reason for change: New Information	(b) (4) Alandra White (b) (4)	12 Mar 2021 13:32:09

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT STATES HER "HEARTBURN HAS BECOME WORSE IN THE PAST MONTH OR SO" START DATE UNKNOWN. SHE WAS PRESCRIBED 20 MG OMEPRAZOLE DAILY. 13 JAN 2021 UPDATE: R. LOWER STOMACH PAIN RESOLVED ON 20 NOV 2020, BUT ACID REFLUX IS STILL ONGOING. THE OMEPRAZOLE 40 MG STARTED BY PCP ON 10 NOV 2020 IS STILL ONGOING AND HAS HELPED SOMEWHAT. AT THIS POINT THERE'S NO PLAN TO INVESTIGATE THIS FURTHER WITH A SPECIALIST. 11 Feb 2021 update: Acid Reflux has been improving for the past several weeks and she's taking the omeprazole 20 mg as needed now (since 26 Jan 2021).' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:40:04
User entered 'PATIENT STATES HER "HEARTBURN HAS BECOME WORSE IN THE PAST MONTH OR SO" START DATE UNKNOWN. SHE WAS PRESCRIBED 20 MG OMEPRAZOLE DAILY.	Yaman Ahmed (b) (4) (b) (4)	13 Jan 2021 20:24:45
13 Jan 2021 update: R. Lower stomach pain resolved on 20 Nov 2020, but acid reflux is still ongoing. The Omeprazole 40 mg started by PCP on 10 Nov 2020 is still ongoing and has helped somewhat. At this point there's no plan to investigate this further with a specialist.' reason for change: Data Entry Error		
User entered 'Patient states her "heartburn has become worse in the past month or so" Start date unknown. She was prescribed 20 mg Omeprazole daily.'	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:59:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 21:36:43

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:07:32
User entered 'USA-US131-2021-mRNA-1273-P301000008'	System	22 Feb 2021 20:18:13
User entered 'New'	(b) (4), (b) (6)	22 Feb 2021 20:18:13

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Female reproductive neoplasms unspecified malignancy, PT: Borderline mucinous tumour of ovary, LLT: Borderline mucinous tumor of ovary - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	07 Apr 2021 18:08:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 18:08:40
User closed query 'PV Query: Thank you for confirming subject experienced pelvic pain. Please consider removing pelvic pain from the event term as it is a symptom of the event.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 20:03:59
Query 'PV Query: Thank you for confirming subject experienced pelvic pain. Please consider removing pelvic pain from the event term as it is a symptom of the event.' answered with 'pelvic pain removed' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:25:10
Data point term sent to Coder	System	06 Apr 2021 19:25:06
User entered 'STAGE 1A MUCINOUS BORDERLINE TUMOR OF THE OVARY WITH INTRAEPITHELIAL CARCINOMA' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User opened query 'PV Query: Thank you for confirming subject experienced pelvic pain. Please consider removing pelvic pain from the event term as it is a symptom of the event.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 22:27:44
Data point term sent to Coder	System	29 Mar 2021 15:25:25
Signature has been broken.	Sharon Mathys (b) (4)	29 Mar 2021 15:25:06
User entered 'PELVIC PAIN RELATED TO Stage 1A mucinous Borderline Tumor of the Ovary with Intraepithelial Carcinoma' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	29 Mar 2021 15:25:06
Data point term sent to Coder	System	15 Mar 2021 14:31:29
User closed query 'For coding purposes, please split PELVIC PAIN RELATED TO PELVIC MASS BELIEVED TO BE A CYSTIC OVARIAN NEOPLASM into separate entries' (Site from System).	System	15 Mar 2021 14:30:45

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Adverse event](#)

Audit	User	Time (GMT)
Query 'For coding purposes, please split PELVIC PAIN RELATED TO PELVIC MASS BELIEVED TO BE A CYSTIC OVARIAN NEOPLASM into separate entries' answered with 'Please try to manually code, or else advise how to properly split the SAE terms for coding/analysis' (Site from System).	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 14:30:45
User opened query 'For coding purposes, please split PELVIC PAIN RELATED TO PELVIC MASS BELIEVED TO BE A CYSTIC OVARIAN NEOPLASM into separate entries' (Site from System).	Coder Import (b) (4) (b) (4)	12 Mar 2021 18:40:47
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User closed query 'PV Query: Please confirm if subject's fall should be reported as an AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 15:07:20
Query 'PV Query: Please confirm if subject's fall should be reported as an AE/SAE.' answered with 'Did not initially go for the fall but the pain possibly shown by the fall. Does not appear to fit ae reporting criteria' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	05 Mar 2021 14:27:40
User opened query 'PV Query: Please confirm if subject's fall should be reported as an AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 21:03:33
Data point term sent to Coder	System	22 Feb 2021 18:47:00
User entered 'Pelvic pain related to pelvic mass believed to be a Cystic Ovarian Neoplasm'	(b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 18:46:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Feb 2021 18:46:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 18:46:49
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 18:46:41
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:18:24
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:18:24
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	14 Apr 2021 15:18:24
	(b) (4)	
User entered '16 Mar 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	14 Apr 2021 15:18:24
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:16:25
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 21:02:37
User entered empty.	System	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'PV Query: Please provide Investigator's rationale for seriousness criteria of Life threatening.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:50:52
Query 'PV Query: Please provide Investigator's rationale for seriousness criteria of Life threatening.' answered with 'Will update after definitive diagnosis. Looks possibly cancerous in origin at this time but not confirmed' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	23 Mar 2021 12:30:21
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	23 Mar 2021 12:29:53
User entered '0' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	23 Mar 2021 12:29:53
User opened query 'PV Query: Please provide Investigator's rationale for seriousness criteria of Life threatening.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 11:36:32
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered '1'	(b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	18 Mar 2021 15:44:39
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	18 Mar 2021 15:44:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Mar 2021 15:43:57
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	18 Mar 2021 15:43:57
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Mar 2021 15:43:57
Signature has been broken.	Yaman Ahmed (b) (4)	18 Mar 2021 15:43:57
User entered '1' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	18 Mar 2021 15:43:57
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	18 Mar 2021 15:43:20
User signature succeeded.	System	18 Mar 2021 15:43:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User closed query 'PV Query: Was the subject hospitalized for longer than 24 hours? If so, please consider adding seriousness criteria of hospitalization and provide admission/discharge dates, when available.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 15:07:26

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'PV Query: Was the subject hospitalized for longer than 24 hours? If so, please consider adding seriousness criteria of hospitalization and provide admission/discharge dates, when available.' answered with 'Subject was discharged from the ed, not admitted to the hospital' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	05 Mar 2021 14:33:07
User opened query 'PV Query: Was the subject hospitalized for longer than 24 hours? If so, please consider adding seriousness criteria of hospitalization and provide admission/discharge dates, when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 21:04:04
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Signature has been broken.	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:43:20
User entered '16 Mar 2021' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:43:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Signature has been broken.	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:43:20
User entered '18 Mar 2021' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:43:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Signature has been broken.	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:44:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:44:39
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Signature has been broken.	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:43:20
User entered '1' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:43:20
User signature succeeded.	(b) (4) Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:19:44
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved' answered with 'updated' (Site from Safety).	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:18:42
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:18:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:18:24
Comment added 'Query Response on 12 Mar 2021 had the wrong date. Meant to be 16 Mar 2021 not 16 Feb 2021.'	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 11:42:34
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 11:35:00
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 11:35:00
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	18 Mar 2021 15:43:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	18 Mar 2021 15:43:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51

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Generated On: 11 Jun 2021 14:59:34

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'surgery planned 16-Feb-2021' (Site from Safety).	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:21:13
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 21:03:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Feb 2021 18:46:41

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Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:46:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SPOKE TO PARTICIPANT TODAY ABOUT PARTICIPANTS TRIP TO THE EMERGENCY ROOM YESTERDAY. SHE HAD SLIPPED AND FALLEN ON ICE 2 DAYS PRIOR TO THE VISIT (2/19/21). SHE HAD ABDOMINAL PAIN (DESCRIBED TO SITE, PER DOCTOR VISIT IT WAS PELVIC PAIN) AFTER THAT. IT WAS INITIALLY MILD, BUT INCREASED TO SEVERE WITH CERTAIN MOVEMENTS. PARTICIPANT HAS A HISTORY OF POLYCYSTIC OVARIAN DISEASE STATUS POST RIGHT OOPHERECTOMY. PARTICIPANT HAD LAB WORK AND CT SCAN. SHE WAS GIVEN MORPHINE 4 MG/ML INJECTION 4 MG (4 MG INTRAVENOUS GIVEN 2/21/21 0957), KETOROLAC (TORADOL) 15 MG/ML INJECTION 15 MG (15 MG INTRAVENOUS GIVEN 2/21/21 0957), ACETAMINOPHEN (TYLENOL) TABLET 975 MG (975 MG ORAL GIVEN 2/21/21 0957), IOPAMIDOL (ISOVUE-300) CONTRAST FOR DILUTION 1,000 ML (1,000 MLS ORAL GIVEN 2/21/21 1013). SHE WAS PRESCRIBED: HYDROCODONE-ACETAMINOPHEN (NORCO) 5-325 MG PER TABLET TAKE 1 TABLET BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN; IBUPROFEN (MOTRIN) 600 MG TABLET ,TAKE 1 TABLET (600 MG TOTAL) BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN. HER LAB WORK APPEARED NORMAL. HOWEVER CT SCAN SHOWED A LARGE PELVCIC MASS THAT IS BELIEVED TO REPRESENT CYSTIC OVARIAN NEOPLASM. THEY WERE UNABLE TO LOCATE THE ORIGIN OF MASS. PARTICIPANT TO SEE OBGYN ONCOLOGY FOR FOLLOW UP AND FURTHER ASSESSMENT OF MASS... 18 MAR 2021 UPDATE: ON 16 MAR 2021 UNDERWENT "EXPLORATION LAPAROTOMY, REMOVAL OF PELVIC MASS, LEFT URETEROLYSIS, TOTAL ABDOMINAL HYSTERECTOMY, RIGHT	System	11 Jun 2021 14:45:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
SALPINGECTOMY, RIGHT URETEROLYSIS, RIGHT OOPHOROPEXY" AND DISCHARGED 18 MAR 2021. RESECTED RETROPERITONEAL MASS (BENIGN CYTOLOGY). 24 MAR 2021 PATHOLOGY REVIEW WAS STAGE 1A MUCINOUS BORDERLINE TUMOR OF THE OVARY WITH INTRAEPITHELIAL CARCINOMA WITH RECOMMENDATION OF SURVEILLANCE. FOLLOW UP GYN-ONC APPOINTMENT SCHEDULED FOR 28-JUN-2021... 14 APR 2021 UPDATE: DOING WELL POST SURGERY AND WILL CONTINUE TO BE MONITORED (TUMOR BOARD ON 24 MAR 2021 RECOMMENDED SURVEILLANCE), WILL HAVE A ABD/PELVIC CT IN JUNE 2021' (WR#5445128) User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SPOKE TO PARTICIPANT TODAY ABOUT PARTICIPANTS TRIP TO THE EMERGENCY ROOM YESTERDAY. SHE HAD SLIPPED AND FALLEN ON ICE 2 DAYS PRIOR TO THE VISIT (2/19/21). SHE HAD ABDOMINAL PAIN (DESCRIBED TO SITE, PER DOCTOR VISIT IT WAS PELVIC PAIN) AFTER THAT. IT WAS INITIALLY MILD, BUT INCREASED TO SEVERE WITH CERTAIN MOVEMENTS. PARTICIPANT HAS A HISTORY OF POLYCYSTIC OVARIAN DISEASE STATUS POST RIGHT OOPHERECTOMY. PARTICIPANT HAD LAB WORK AND CT SCAN. SHE WAS GIVEN MORPHINE 4 MG/ML INJECTION 4 MG (4 MG INTRAVENOUS GIVEN 2/21/21 0957), KETOROLAC (TORADOL) 15 MG/ML INJECTION 15 MG (15 MG INTRAVENOUS GIVEN 2/21/21 0957), ACETAMINOPHEN (TYLENOL) TABLET 975 MG (975 MG ORAL GIVEN 2/21/21 0957), IOPAMIDOL (ISOVUE-300) CONTRAST FOR DILUTION 1,000 ML (1,000 MLS ORAL GIVEN 2/21/21 1013). SHE WAS PRESCRIBED: HYDROCODONE-ACETAMINOPHEN (NORCO) 5-325 MG PER TABLET TAKE 1 TABLET BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN: IBUPROFEN (MOTRIN) 600 MG TABLET ,TAKE 1 TABLET (600 MG TOTAL) BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN. HER LAB WORK APPEARED NORMAL. HOWEVER CT SCAN SHOWED A LARGE PELVCIC MASS THAT IS BELIEVED TO REPRESENT CYSTIC OVARIAN NEOPLASM. THEY WERE UNABLE TO LOCATE THE ORIGIN OF MASS. PARTICIPANT TO SEE OBGYN ONCOLOGY FOR FOLLOW UP AND FURTHER ASSESSMENT OF MASS... 18 MAR 2021 UPDATE: ON 16 MAR 2021 UNDERWENT "EXPLORATION LAPAROTOMY, REMOVAL OF PELVIC MASS, LEFT URETEROLYSIS, TOTAL	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
ABDOMINAL HYSTERECTOMY, RIGHT SALPINGECTOMY, RIGHT URETEROLYSIS, RIGHT OOPHOROPEXY" AND DISCHARGED 18 MAR 2021. RESECTED RETROPERITONEAL MASS (BENIGN CYTOLOGY). 24 MAR 2021 PATHOLOGY REVIEW WAS STAGE 1A MUCINOUS BORDERLINE TUMOR OF THE OVARY WITH INTRAEPITHELIAL CARCINOMA WITH RECOMMENDATION OF SURVEILLANCE. FOLLOW UP GYN-ONC APPOINTMENT SCHEDULED FOR 28-JUN-2021... 14 Apr 2021 update: doing well post surgery and will continue to be monitored (tumor board on 24 Mar 2021 recommended surveillance), will have a abd/pelvic CT in June 2021' reason for change: New Information		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SPOKE TO PARTICIPANT TODAY ABOUT PARTICIPANTS TRIP TO THE EMERGENCY ROOM YESTERDAY. SHE HAD SLIPPED AND FALLEN ON ICE 2 DAYS PRIOR TO THE VISIT (2/19/21). SHE HAD ABDOMINAL PAIN (DESCRIBED TO SITE, PER DOCTOR VISIT IT WAS PELVIC PAIN) AFTER THAT. IT WAS INITIALLY MILD, BUT INCREASED TO SEVERE WITH CERTAIN MOVEMENTS. PARTICIPANT HAS A HISTORY OF POLYCYSTIC OVARIAN DISEASE STATUS POST RIGHT OOPHERECTOMY. PARTICIPANT HAD LAB WORK AND CT SCAN. SHE WAS GIVEN MORPHINE 4 MG/ML INJECTION 4 MG (4 MG INTRAVENOUS GIVEN 2/21/21 0957), KETOROLAC (TORADOL) 15 MG/ML INJECTION 15 MG (15 MG INTRAVENOUS GIVEN 2/21/21 0957), ACETAMINOPHEN (TYLENOL) TABLET 975 MG (975 MG ORAL GIVEN 2/21/21 0957), IOPAMIDOL (ISOVUE-300) CONTRAST FOR DILUTION 1,000 ML (1,000 MLS ORAL GIVEN 2/21/21 1013). SHE WAS PRESCRIBED: HYDROCODONE-ACETAMINOPHEN (NORCO) 5-325 MG PER TABLET TAKE 1 TABLET BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN: IBUPROFEN (MOTRIN) 600 MG TABLET ,TAKE 1 TABLET (600 MG TOTAL) BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN. HER LAB WORK APPEARED NORMAL. HOWEVER CT SCAN SHOWED A LARGE PELVCIC MASS THAT IS BELIEVED TO REPRESENT CYSTIC OVARIAN NEOPLASM. THEY WERE UNABLE TO LOCATE THE ORIGIN OF MASS. PARTICIPANT TO SEE OBGYN ONCOLOGY FOR FOLLOW UP AND FURTHER ASSESSMENT OF MASS... 18 MAR 2021 UPDATE: ON 16 MAR 2021 UNDERWENT "EXPLORATION LAPAROTOMY, REMOVAL OF PELVIC MASS, LEFT URETEROLYSIS, TOTAL	(b) (4), (b) (6)	13 Apr 2021 12:31:25

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
ABDOMINAL HYSTERECTOMY, RIGHT SALPINGECTOMY, RIGHT URETEROLYSIS, RIGHT OOPHOROPEXY" AND DISCHARGED 18 MAR 2021. RESECTED RETROPERITONEAL MASS (BENIGN CYTOLOGY). 24 MAR 2021 PATHOLOGY REVIEW WAS STAGE 1A MUCINOUS BORDERLINE TUMOR OF THE OVARY WITH INTRAEPITHELIAL CARCINOMA WITH RECOMMENDATION OF SURVEILLANCE. Follow up GYN-ONC appointment scheduled for 28-JUN-2021' reason for change: New Information		
User closed query 'PV query: Please provide final diagnosis for pelvic mass if known.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 20:03:52
User closed query 'PV query: Please provide hospital records, including discharge summary, operative report, and pathology report. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 20:03:49
Query 'PV query: Please provide hospital records, including discharge summary, operative report, and pathology report. ' answered with 'has been sent to safety email' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	05 Apr 2021 12:51:55
Query 'PV query: Please provide final diagnosis for pelvic mass if known.' answered with 'STAGE 1A MUCINOUS BORDERLINE TUMOR OF THE OVARY WITH INTRAEPITHELIAL CARCINOMA' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	05 Apr 2021 12:51:45
User closed query 'PV Query: Please consider whether pelvic mass meets SAE reporting criteria as an additional event. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:46:33
User closed query 'PV Query: It was reported in an answered query regarding end date and outcome that the subject had a planned surgery on 16 Feb 2021 but the event occurred days after this. Was this surgery for another AE?' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:39:41
User closed query 'PV Query: Please clarify if the pain was abdominal or pelvic' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:39:26

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Audit	User	Time (GMT)
Query 'PV Query: Please consider whether pelvic mass meets SAE reporting criteria as an additional event. ' answered with 'Please advise whether this should be listed as pelvic pain or just the diagnosis as they are inter-related and the pain itself isn't the issue but the cause of the pain is.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	29 Mar 2021 15:25:57

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SPOKE TO PARTICIPANT TODAY ABOUT PARTICIPANTS TRIP TO THE EMERGENCY ROOM YESTERDAY. SHE HAD SLIPPED AND FALLEN ON ICE 2 DAYS PRIOR TO THE VISIT (2/19/21). SHE HAD ABDOMINAL PAIN (DESCRIBED TO SITE, PER DOCTOR VISIT IT WAS PELVIC PAIN) AFTER THAT. IT WAS INITIALLY MILD, BUT INCREASED TO SEVERE WITH CERTAIN MOVEMENTS. PARTICIPANT HAS A HISTORY OF POLYCYSTIC OVARIAN DISEASE STATUS POST RIGHT OOPHERECTOMY. PARTICIPANT HAD LAB WORK AND CT SCAN. SHE WAS GIVEN MORPHINE 4 MG/ML INJECTION 4 MG (4 MG INTRAVENOUS GIVEN 2/21/21 0957), KETOROLAC (TORADOL) 15 MG/ML INJECTION 15 MG (15 MG INTRAVENOUS GIVEN 2/21/21 0957), ACETAMINOPHEN (TYLENOL) TABLET 975 MG (975 MG ORAL GIVEN 2/21/21 0957), IOPAMIDOL (ISOVUE-300) CONTRAST FOR DILUTION 1,000 ML (1,000 MLS ORAL GIVEN 2/21/21 1013). SHE WAS PRESCRIBED: HYDROCODONE-ACETAMINOPHEN (NORCO) 5-325 MG PER TABLET TAKE 1 TABLET BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN: IBUPROFEN (MOTRIN) 600 MG TABLET ,TAKE 1 TABLET (600 MG TOTAL) BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN. HER LAB WORK APPEARED NORMAL. HOWEVER CT SCAN SHOWED A LARGE PELVCIC MASS THAT IS BELIEVED TO REPRESENT CYSTIC OVARIAN NEOPLASM. THEY WERE UNABLE TO LOCATE THE ORIGIN OF MASS. PARTICIPANT TO SEE OBGYN ONCOLOGY FOR FOLLOW UP AND FURTHER ASSESSMENT OF MASS... 18 MAR 2021 UPDATE: ON 16 MAR 2021 UNDERWENT "EXPLORATION LAPAROTOMY, REMOVAL OF PELVIC MASS, LEFT URETEROLYSIS, TOTAL	Sharon Mathys (b) (4) (b) (4)	29 Mar 2021 15:25:06

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
ABDOMINAL HYSTERECTOMY, RIGHT SALPINGECTOMY, RIGHT URETEROLYSIS, RIGHT OOPHOROPEXY" AND DISCHARGED 18 MAR 2021. RESECTED RETROPERITONEAL MASS (BENIGN CYTOLOGY). 24 mar 2021 Pathology review was Stage 1A mucinous borderline tumor of the ovary with intraepithelial carcinoma with recommendation of surveillance.' reason for change: New Information Query 'PV Query: Please clarify if the pain was abdominal or pelvic' answered with 'Participant described to staff abdominal pain, but per doctors notes it was pelvic pain. Added to narrative.' (Site from Safety). Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 11:40:32
	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 11:39:57

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Form: Adverse Events (3)

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Audit	User	Time (GMT)
User entered 'SPOKE TO PARTICIPANT TODAY ABOUT PARTICIPANTS TRIP TO THE EMERGENCY ROOM YESTERDAY. SHE HAD SLIPPED AND FALLEN ON ICE 2 DAYS PRIOR TO THE VISIT (2/19/21). SHE HAD ABDOMINAL PAIN (described to site, per doctor visit it was pelvic pain) AFTER THAT. IT WAS INITIALLY MILD, BUT INCREASED TO SEVERE WITH CERTAIN MOVEMENTS. PARTICIPANT HAS A HISTORY OF POLYCYSTIC OVARIAN DISEASE STATUS POST RIGHT OOPHERECTOMY. PARTICIPANT HAD LAB WORK AND CT SCAN. SHE WAS GIVEN MORPHINE 4 MG/ML INJECTION 4 MG (4 MG INTRAVENOUS GIVEN 2/21/21 0957), KETOROLAC (TORADOL) 15 MG/ML INJECTION 15 MG (15 MG INTRAVENOUS GIVEN 2/21/21 0957), ACETAMINOPHEN (TYLENOL) TABLET 975 MG (975 MG ORAL GIVEN 2/21/21 0957), IOPAMIDOL (ISOVUE-300) CONTRAST FOR DILUTION 1,000 ML (1,000 MLS ORAL GIVEN 2/21/21 1013). SHE WAS PRESCRIBED: HYDROCODONE-ACETAMINOPHEN (NORCO) 5-325 MG PER TABLET TAKE 1 TABLET BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN IBUPROFEN (MOTRIN) 600 MG TABLET TAKE 1 TABLET (600 MG TOTAL) BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN. HER LAB WORK APPEARED NORMAL. HOWEVER CT SCAN SHOWED A LARGE PELVIC MASS THAT IS BELIEVED TO REPRESENT CYSTIC OVARIAN NEOPLASM. THEY WERE UNABLE TO LOCATE THE ORIGIN OF MASS. PARTICIPANT TO SEE OBGYN ONCOLOGY FOR FOLLOW UP AND FURTHER ASSESSMENT OF MASS... 18 MAR 2021 UPDATE: ON 16 MAR 2021 UNDERWENT "EXPLORATION LAPAROTOMY, REMOVAL OF PELVIC MASS, LEFT URETEROLYSIS, TOTAL ABDOMINAL	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 11:39:57

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Audit	User	Time (GMT)
<p>HYSTERECTOMY, RIGHT SALPINGECTOMY, RIGHT URETEROLYSIS, RIGHT OOPHOROPEXY" AND DISCHARGED 18 MAR 2021. RESECTED RETROPERITONEAL MASS (BENIGN CYTOLOGY).' reason for change: New Information</p>		
Query 'PV Query: It was reported in an answered query regarding end date and outcome that the subject had a planned surgery on 16 Feb 2021 but the event occurred days after this. Was this surgery for another AE?' answered with 'Please tell us where to find that query as since this event started on 19 feb after a fall, there isn't any way the surgery was mentioned in the narrative here (I have checked queries). Please tell us where to find this statement (form/question)' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 11:39:01
User opened query 'PV query: Please provide hospital records, including discharge summary, operative report, and pathology report. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:07:38
User opened query 'PV Query: Please consider whether pelvic mass meets SAE reporting criteria as an additional event. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:07:29
User opened query 'PV Query: It was reported in an answered query regarding end date and outcome that the subject had a planned surgery on 16 Feb 2021 but the event occurred days after this. Was this surgery for another AE?' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:07:19
User closed query 'PV Query: It was reported that the subject had a planned surgery on 16 Feb 2021 but the event occurred days after this. Was this surgery for another AE?' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 12:51:03
Query 'PV Query: It was reported that the subject had a planned surgery on 16 Feb 2021 but the event occurred days after this. Was this surgery for another AE?' answered with 'Unsure where you are referring to 16 feb 2021 as inciting incident was 19 feb 2021 and it was not reported in safety calls on review. Please point out where it mentioned 16 feb 2021' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	23 Mar 2021 12:24:03
User opened query 'PV query: Please provide final diagnosis for pelvic mass if known.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 11:36:58

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EAB) (1725)

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Audit	User	Time (GMT)
User opened query 'PV Query: It was reported that the subject had a planned surgery on 16 Feb 2021 but the event occurred days after this. Was this surgery for another AE?' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 11:36:04
User opened query 'PV Query: Please clarify if the pain was abdominal or pelvic' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 11:35:45
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Signature has been broken.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Mar 2021 15:43:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SPOKE TO PARTICIPANT TODAY ABOUT PARTICIPANTS TRIP TO THE EMERGENCY ROOM YESTERDAY. SHE HAD SLIPPED AND FALLEN ON ICE 2 DAYS PRIOR TO THE VISIT (2/19/21). SHE HAD ABDOMINAL PAIN AFTER THAT. IT WAS INITIALLY MILD, BUT INCREASED TO SEVERE WITH CERTAIN MOVEMENTS. PARTICIPANT HAS A HISTORY OF POLYCYSTIC OVARIAN DISEASE STATUS POST RIGHT OOPHERECTOMY. PARTICIPANT HAD LAB WORK AND CT SCAN. SHE WAS GIVEN MORPHINE 4 MG/ML INJECTION 4 MG (4 MG INTRAVENOUS GIVEN 2/21/21 0957), KETOROLAC (TORADOL) 15 MG/ML INJECTION 15 MG (15 MG INTRAVENOUS GIVEN 2/21/21 0957), ACETAMINOPHEN (TYLENOL) TABLET 975 MG (975 MG ORAL GIVEN 2/21/21 0957), IOPAMIDOL (ISOVUE-300) CONTRAST FOR DILUTION 1,000 ML (1,000 MLS ORAL GIVEN 2/21/21 1013). SHE WAS PRESCRIBED: HYDROCODONE-ACETAMINOPHEN (NORCO) 5-325 MG PER TABLET TAKE 1 TABLET BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN IBUPROFEN (MOTRIN) 600 MG TABLET TAKE 1 TABLET (600 MG TOTAL) BY MOUTH EVERY 6 (SIX) HOURS AS NEEDED FOR PAIN. HER LAB WORK APPEARED NORMAL. HOWEVER CT SCAN SHOWED A LARGE PELVIC MASS THAT IS BELIEVED TO REPRESENT CYSTIC OVARIAN NEOPLASM. THEY WERE UNABLE TO LOCATE THE ORIGIN OF MASS. PARTICIPANT TO SEE OBGYN ONCOLOGY FOR FOLLOW UP AND FURTHER ASSESSMENT OF MASS... 18 Mar 2021 update: On 16 Mar 2021 underwent "EXPLORATION LAPAROTOMY, REMOVAL OF PELVIC MASS, LEFT URETEROLYSIS, TOTAL ABDOMINAL HYSTERECTOMY, RIGHT SALPINGECTOMY, RIGHT URETEROLYSIS,	Yaman Ahmed (b) (4) (b) (4)	18 Mar 2021 15:43:20

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Audit	User	Time (GMT)
RIGHT OOPHOROPEXY" and discharged 18 Mar 2021. Resected retroperitoneal mass (benign cytology).' reason for change: New Information		
User closed query 'Per DM CLR: Narrative = PARTICIPANT HAD LAB WORK AND CT SCAN. However, this is 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)	15 Mar 2021 03:14:21
User closed query 'Per DM CLR: Narrative = FALLEN. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 03:13:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
Query 'Per DM CLR: Narrative = PARTICIPANT HAD LAB WORK AND CT SCAN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added to conproc folder ' (Site from DM).	Alandra White (b) (4)	12 Mar 2021 13:36:43
Query 'Per DM CLR: Narrative = FALLEN. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'does not meet reporting criteria ' (Site from DM).	Alandra White (b) (4)	12 Mar 2021 13:36:26
User opened query 'Per DM CLR: Narrative = PARTICIPANT HAD LAB WORK AND CT SCAN. However, this is 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)	09 Mar 2021 00:51:07
User opened query 'Per DM CLR: Narrative = FALLEN. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:51:01

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Spoke to participant today about participants trip to the Emergency Room yesterday. She had slipped and fallen on ice 2 days prior to the visit (2/19/21). She had abdominal pain after that. It was initially mild, but increased to severe with certain movements. Participant has a history of polycystic ovarian disease status post right oophorectomy. Participant had lab work and CT scan. She was given morphine 4 mg/mL injection 4 mg (4 mg Intravenous Given 2/21/21 0957), ketorolac (TORADOL) 15 mg/mL injection 15 mg (15 mg Intravenous Given 2/21/21 0957), acetaminophen (TYLENOL) tablet 975 mg (975 mg Oral Given 2/21/21 0957), iopamidol (ISOVUE-300) contrast for dilution 1,000 mL (1,000 mLs Oral Given 2/21/21 1013). She was prescribed: HYDROCODONE-ACETAMINOPHEN (NORCO) 5-325 MG PER TABLET Take 1 tablet by mouth every 6 (six) hours as needed for pain IBUPROFEN (MOTRIN) 600 MG TABLET Take 1 tablet (600 mg total) by mouth every 6 (six) hours as needed for pain. Her lab work appeared normal. However CT scan showed a large pelvic mass that is believed to represent Cystic Ovarian Neoplasm. They were unable to locate the origin of mass. Participant to see OBGYN Oncology for follow up and further assessment of mass.'	(b) (4), (b) (6)	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 18:46:41

US3522173

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:59:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 15:44:39

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness in leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:55:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:55:01
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
Data point term sent to Coder	System	14 Apr 2021 15:15:35
User entered 'left upper thigh numbness'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	14 Apr 2021 15:15:30
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered '16 Mar 2021'	(b) (4) Yaman Ahmed (b) (4)	14 Apr 2021 15:15:30
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Yaman Ahmed (b) (4)	14 Apr 2021 15:15:30
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Yaman Ahmed (b) (4)	14 Apr 2021 15:15:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Yaman Ahmed (b) (4)	14 Apr 2021 15:15:30
	(b) (4)	

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'Not Applicable (NOT APPLICABLE)'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'I'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Yaman Ahmed (b) (4)	14 Apr 2021 15:15:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered 'Has a follow-up with PCP on 26 Apr 2021 when she will address a numbness in left upper thigh since post surgery 16 Mar 2021. Post surgery she had lower back pain and left leg pain, which improved somewhat but not completely gone.'	(b) (4) Yaman Ahmed (b) (4)	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 15:15:30

US3522173

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 14:59:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 15:15:30

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Jun 2021 14:59:34

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:16
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:30:52

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 19:46:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 19:46:43
Data point term sent to Coder Coding entries removed.	System Kristin Eis (b) (4)	29 Sep 2020 19:45:27 29 Sep 2020 19:44:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 19:44:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 19:44:51
Data point term sent to Coder Coding entries removed.	System Kristin Eis (b) (4)	29 Sep 2020 19:43:22 29 Sep 2020 19:42:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 19:40:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 19:40:42
Data point term sent to Coder Coding entries removed.	System Kristin Eis (b) (4)	29 Sep 2020 19:39:11 29 Sep 2020 19:39:05

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Aug 2020 12:32:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Aug 2020 12:32:27
Data point term sent to Coder	System	18 Aug 2020 12:32:11
User entered 'Metformin'	Yaman Ahmed (b) (4)	18 Aug 2020 12:31:42
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User closed query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 09:19:46
User entered 'PRE-DIABETIC' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 19:44:56
User entered 'PCOS' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 19:42:29
Query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' answered with 'fixed ' (Site from DM).	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 19:39:11
User entered 'Diabetes' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 19:39:05
User opened query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:17:48
User entered 'PCOS'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '500'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:31:42
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:31:42
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'once daily (QD)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:31:42
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:31:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:31:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'I'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:31:42
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:31:42
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 12:31:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 07:08:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:08:26
Data point term sent to Coder	System	18 Aug 2020 12:33:12
User entered 'Ventolin'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Mild Asthma'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:32:57
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'Unknown'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'puff (PUFF)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:32:57
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'as needed (PRN)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:32:57
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:32:57
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Aug 2020 12:32:57
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 12:32:57

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 15:00:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 15:00:34
Data point term sent to Coder	System	10 Nov 2020 19:18:13
User entered 'Omeprazole'	Yaman Ahmed (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'lower right stomach pain'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered '40'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'twice daily (BID)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '10 Nov 2020'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 08:20:00
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'confirmed stoppage' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:10:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:10:05
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:39:57
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4)	29 Jan 2021 13:10:05
User entered empty.	Yaman Ahmed (b) (4)	10 Nov 2020 19:17:49
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User entered '2'	System	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User entered '1'	System	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:48:56
User entered '804 (804)'	System	10 Nov 2020 19:17:49

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User closed query 'Per DM CLR: Please review ConMed #s 3 and 4, as both medication were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 07:19:55
Query 'Per DM CLR: Please review ConMed #s 3 and 4, as both medication were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:11:56
User opened query 'Per DM CLR: Please review ConMed #s 3 and 4, as both medication were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:58:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 21:38:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 21:38:44
Data point term sent to Coder	System	14 Dec 2020 21:37:43
User entered 'omeprazole'	(b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 11:51:48
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'not pprophylactic' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:12:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:12:12
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:58:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'acid reflux'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '20'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:40:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered '26 Jan 2021' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:40:38
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User entered '1'	System	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User entered '1'	System	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:03
User entered '804 (804)'	System	14 Dec 2020 21:37:42

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
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)	17 Dec 2020 22:19:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Dec 2020 22:19:45
Data point term sent to Coder	System	14 Dec 2020 21:38:44
User entered 'influenza quad with preservative'	(b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'prevention of influenza'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0.5'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User entered empty.	System	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User entered empty.	System	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:10
User entered empty.	System	14 Dec 2020 21:38:37

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 26 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). Query 'Per DM CLR: this Con Med was added/ had dose increased on 26 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'reduced dose from 20 Nov 2020, AE still ongoing' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:51:03
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 26 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 18:23:39
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 26 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 01:23:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 17:42:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 17:42:54
Data point term sent to Coder	System	11 Feb 2021 17:41:49
User entered 'Omeprazole'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Acid Reflux'	(b) (4) Yaman Ahmed (b) (4)	11 Feb 2021 17:41:27
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered '20'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'as needed (PRN)'	(b) (4) Yaman Ahmed (b) (4)	11 Feb 2021 17:41:27
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '26 Jan 2021'	(b) (4) Yaman Ahmed (b) (4)	11 Feb 2021 17:41:27
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:41:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Feb 2021 07:10:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:10:07
Data point term sent to Coder	System	22 Feb 2021 18:54:12
User entered 'Morphine'	(b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'pelvic mass'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '4'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User entered empty.	System	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User entered empty.	System	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:21
User entered empty.	System	22 Feb 2021 18:53:38

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 06:35:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 06:35:07
Data point term sent to Coder	System	22 Feb 2021 19:00:19
User entered 'ketorolac'	(b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Pelvic pain related to pelvic mass'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '15'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User entered '1'	System	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User entered '1'	System	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:23
User entered '804 (804)'	System	22 Feb 2021 18:59:43

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Feb 2021 19:04:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 19:04:02
Data point term sent to Coder	System	22 Feb 2021 19:03:23
User entered 'Tylenol'	(b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Pain related to pelvic mass'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '975'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User entered empty.	System	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User entered empty.	System	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:25
User entered empty.	System	22 Feb 2021 19:02:24

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 11:26:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 11:26:59
Data point term sent to Coder	System	22 Feb 2021 19:03:23
User entered 'Iopamidol contrast'	(b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'CT scan related to pain from pelvic mass'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '1000'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User entered empty.	System	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User entered empty.	System	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:30
User entered empty.	System	22 Feb 2021 19:03:20

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 13:27:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 13:27:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	16 Mar 2021 18:26:38 16 Mar 2021 18:26:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Mar 2021 11:30:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Mar 2021 11:30:57
Data point term sent to Coder User entered 'Hydrocodone-Acetaminophen (NORCO)'	System (b) (4), (b) (6)	22 Feb 2021 19:05:25 22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:44:22
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. answered with 'fixed' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 18:26:12
User entered 'PELVIC PAIN RELATED TO PELVIC MASS BELIEVED TO BE A CYSTIC OVARIAN NEOPLASM' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 18:26:08
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 01:24:10
User entered 'pain related to abdominal mass'	(b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '5-325'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'As needed every six hours'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:04:27

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Mar 2021 19:58:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Mar 2021 19:58:08
Data point term sent to Coder	System	22 Feb 2021 19:05:25
User entered 'Ibuprofen'	(b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Pain related to pelvic mass'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '600'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'As needed every six hours'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:05:06

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:35:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:35:25
Data point term sent to Coder	System	15 Apr 2021 11:28:34
Query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:27:44
User opened query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. '(Site from System).	Coder Import (b) (4) (b) (4)	15 Apr 2021 10:57:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
Data point term sent to Coder	System	14 Apr 2021 15:23:58
Data point term sent to Coder	System	14 Apr 2021 15:22:57
User entered 'Lovenox'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered 'post surgical DVT prophylaxis' reason for change: Data Entry Error	(b) (4)	
	Yaman Ahmed (b) (4)	14 Apr 2021 15:23:35
	(b) (4)	
User entered 'DVT'	Yaman Ahmed (b) (4)	14 Apr 2021 15:21:48
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 15:23:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 15:23:17
User entered '40' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	14 Apr 2021 15:23:17
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 15:21:48
User entered empty.	Yaman Ahmed (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 15:23:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 15:23:17
User entered 'mg (mg)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	14 Apr 2021 15:23:17
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 15:21:48
User entered empty.	Yaman Ahmed (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 15:23:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 15:23:17
User entered 'once daily (QD)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	14 Apr 2021 15:23:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 15:21:48
User entered empty.	System	14 Apr 2021 15:21:48
	Yaman Ahmed (b) (4)	14 Apr 2021 15:21:48
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 15:23:17
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	System	14 Apr 2021 15:23:17
User opened query 'Data is required. Please complete.' (Site from System).	Yaman Ahmed (b) (4)	14 Apr 2021 15:23:17
User entered empty.	(b) (4)	
	System	14 Apr 2021 15:21:48
	Yaman Ahmed (b) (4)	14 Apr 2021 15:21:48
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	14 Apr 2021 15:23:17
User entered '18 Mar 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	14 Apr 2021 15:23:17
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Apr 2021 15:21:48
User entered empty.	Yaman Ahmed (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 15:23:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 15:23:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	14 Apr 2021 15:23:17
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 15:21:48
User entered empty.	Yaman Ahmed (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:32:53
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 15:23:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 15:23:17
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	14 Apr 2021 15:23:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 15:21:48
User entered empty.	System	14 Apr 2021 15:21:48
	Yaman Ahmed (b) (4)	14 Apr 2021 15:21:48
	(b) (4)	

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 15:23:17
User entered empty.	System	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 15:23:17
User entered empty.	System	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 14:59:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Apr 2021 15:23:17
User entered empty.	System	14 Apr 2021 15:21:48

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Jun 2021 14:59:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:16
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
Signature has been broken.	(b) (4) Alandra White (b) (4)	12 Mar 2021 12:21:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Alandra White (b) (4)	12 Mar 2021 12:21:40
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'No (N)'	(b) (4) Kristin Eis (b) (4)	15 Sep 2020 12:36:49

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 14:59:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered '21 Feb 2021' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:24:10
User entered '12 Mar 2021'	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:23:30

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 14:59:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	18 Mar 2021 15:31:54
	(b) (4)	
User entered 'CT SCAN, ABDOMEN/pelvis' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	18 Mar 2021 15:31:54
User signature succeeded.	(b) (4)	
	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
	(b) (4)	
User entered 'Ct scan, abdomen'	Alandra White (b) (4)	12 Mar 2021 12:23:30
	(b) (4)	

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'Adverse Event (AE)'	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:23:30

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 14:59:34

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:23:30

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 14:59:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:16
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered '21 Feb 2021'	(b) (4) Alandra White (b) (4)	12 Mar 2021 12:25:24

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 14:59:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:16
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered 'lab work'	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:25:24

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:16
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:17:51
User entered 'Adverse Event (AE)'	(b) (4) Alandra White (b) (4)	12 Mar 2021 12:25:24

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 14:59:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:16
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:17:51
User entered empty.	Alandra White (b) (4) (b) (4)	12 Mar 2021 12:25:24

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 14:59:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:26
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '16 Mar 2021'	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:34:22

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 14:59:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:26
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Exploration laparotomy, removal of pelvic mass, left ureterolysis, total abdominal hysterectomy, right salpingectomy, right ureterolysis, right oophoropexy'	Yaman Ahmed (b) (4)	18 Mar 2021 15:34:22

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 14:59:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:26
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered 'Adverse Event (AE)'	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:34:22

US3522173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 14:59:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:26
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Mar 2021 15:34:22

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) ,	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 14:59:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered '22/Feb/2021 14:18'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 14:59:34

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)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 14:59:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:36:35
User entered '08/Mar/2021 09:07'	(b) (4) System	08 Mar 2021 15:07:58

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 14:59:34

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)	19 Mar 2021 13:36:02
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:36:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:07:58

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 14:59:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '19/Mar/2021 09:36'	(b) (4) System	19 Mar 2021 13:36:12

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 14:59:34

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)	24 Mar 2021 12:52:30
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:12

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) ,	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 14:59:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
User entered '24/Mar/2021 08:52'	(b) (4) System	24 Mar 2021 12:52:47

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 14:59:34

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)	29 Mar 2021 16:47:54
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:47

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) ,	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 14:59:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:09
User entered '29/Mar/2021 12:48'	(b) (4) System	29 Mar 2021 16:48:10

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 14:59:34

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)	06 Apr 2021 20:04:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:09
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:48:10

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) ,	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 11 Jun 2021 14:59:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:55:13
User entered '06/Apr/2021 16:04'	(b) (4) System	06 Apr 2021 20:04:20

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 11 Jun 2021 14:59:34

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.	Marcus Zervos (b) (4)	12 Apr 2021 11:55:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:27:09
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 20:04:20

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) ,	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 11 Jun 2021 14:59:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:55:13
User entered '07/Apr/2021 09:27'	(b) (4) System	07 Apr 2021 13:27:06

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 11 Jun 2021 14:59:34

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.	Marcus Zervos (b) (4)	12 Apr 2021 11:55:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:27:09
User entered '1'	(b) (4), (b) (6)	07 Apr 2021 13:27:06

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'USA-US131-2021-MRNA-1273-P301000008'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:52:30
Un-reviewed for Safety.	System	23 Mar 2021 12:29:53
Signature has been broken.	System	23 Mar 2021 12:29:53
User entered 'No (N)'	System	23 Mar 2021 12:29:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Yes (Y)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
Un-reviewed for Safety.	System	18 Mar 2021 15:43:57
Signature has been broken.	System	18 Mar 2021 15:43:57
User entered 'Yes (Y)'	System	18 Mar 2021 15:43:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'No (N)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Paul'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'Kilgore'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6) '	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered 'MI'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:18:25
User entered (b) (6)'	System	22 Feb 2021 20:18:13

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:07:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:35:51
User entered 'US'	(b) (4) System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Jun 2021 14:59:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	14 Apr 2021 19:20:11
User entered '7'	System	07 Apr 2021 13:27:06
User entered '6'	System	06 Apr 2021 20:04:20
User entered '5'	System	29 Mar 2021 16:48:10
User entered '4'	System	24 Mar 2021 12:52:47
User entered '3'	System	19 Mar 2021 13:36:12
User entered '2'	System	08 Mar 2021 15:07:58
User entered '1'	System	22 Feb 2021 20:18:34

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 11 Jun 2021 14:59:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered '14/Apr/2021 14:20'	(b) (4) System	14 Apr 2021 19:20:11

US3522173

Folder: SAE USA-US131-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 11 Jun 2021 14:59:34

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.	Marcus Zervos (b) (4)	14 Apr 2021 22:32:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:20:11