

US3372060 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:11:41

All time stamps listed in this document are displayed in GMT

US3372060

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 16:26:10

Generated On: 09 Jun 2021 17:11:41

[Participant ID](#)

US3372060

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

US3372060

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Condition	TORN MENISCUS RIGHT KNEE
Start date (dd MMM yyyy)	UN APR 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 1996
Stop date completely unknown	False
Start Month and Year (derived)	APR 1996
Start Year (derived)	1996
Stop Month and Year (derived)	APR 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Condition	ARTHROPLASTY RIGHT KNEE
Start date (dd MMM yyyy)	UN APR 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 1996
Stop date completely unknown	False
Start Month and Year (derived)	APR 1996
Start Year (derived)	1996
Stop Month and Year (derived)	APR 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN SEP 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2014
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2014
Start Year (derived)	2014
Stop Month and Year (derived)	SEP 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Condition	CORONARY ARTERY ANGIOPLASTY
Start date (dd MMM yyyy)	UN SEP 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2014
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2014
Start Year (derived)	2014
Stop Month and Year (derived)	SEP 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Condition	CHRONIC PANCREATITIS
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372060

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 10:30
Height (<i>xxx.x</i>)	169.9 cm
Weight (<i>xxx.x</i>)	82 kg
BMI (<i>xxx.x</i>)	28.40711 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) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 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: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:26:52

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☒ No ☐

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

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) 15 Feb 2021 16:26:52

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 27 Apr 2021 01:40:01

Generated On: 09 Jun 2021 17:11:41

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 101380

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) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

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) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 10:30
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	12:52 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 12:52
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

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) 7 AUG 2020

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 12:13

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) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 AUG 2020

Collection time (00:00-23:59)

11:19 (24 HR)

Collection date and time (derived)

7 AUG 2020 11:19

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Collection date (dd MMM yyyy)			7 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:17	7 AUG 2020 11:17
Nasopharyngeal Swab 2	No		

US3372060

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:51

PC Open Date & Time

07 AUG 2020 12:33

PC Close Date & Time

07 AUG 2020 15:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 97.2 °F

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

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

PC Time Stamp	07 AUG 2020 21:24
PC Open Date & Time	07 AUG 2020 15:58
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 18:41

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

09 AUG 2020 19:20

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

97.3 °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

10 AUG 2020 22:28

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

11 AUG 2020 20:45

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 19:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

13 AUG 2020 21:12

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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

07 AUG 2020 12:53

PC Open Date & Time

07 AUG 2020 12:33

PC Close Date & Time

07 AUG 2020 15:03

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

07 AUG 2020 21:25

PC Open Date & Time

07 AUG 2020 15:58

PC Close Date & Time

08 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 18:41

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:21

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

10 AUG 2020 22:28

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 20:45

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 19:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 21:12

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 12:53
PC Open Date & Time	07 AUG 2020 12:33
PC Close Date & Time	07 AUG 2020 15:03

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 21:26
PC Open Date & Time	07 AUG 2020 15:58
PC Close Date & Time	08 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2333

EAB) (1725)

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:42
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2333

EAB) (1725)

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:21
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

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 ☒

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 22:28
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2333

EAB) (1725)

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 20:46
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

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 ☒

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:12
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:34
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:11
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 11:34 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 11:34

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

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

10:58 (24 HR)

Collection date and time (derived)

10 SEP 2020 10:58

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:57	10 SEP 2020 10:57
Nasopharyngeal Swab 2	No		

US3372060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:10

PC Open Date & Time

10 SEP 2020 11:54

PC Close Date & Time

10 SEP 2020 14:24

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	10 SEP 2020 19:48
PC Open Date & Time	10 SEP 2020 15:19
PC Close Date & Time	11 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

12 SEP 2020 22:15

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 22:40

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

15 SEP 2020 09:38

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

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

94.3 °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 21:29

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:38

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

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

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

10 SEP 2020 12:11

PC Open Date & Time

10 SEP 2020 11:54

PC Close Date & Time

10 SEP 2020 14:24

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

10 SEP 2020 19:48

PC Open Date & Time

10 SEP 2020 15:19

PC Close Date & Time

11 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 22:15

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

13 SEP 2020 22:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 09:38

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:30

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 20:38

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 12:11
PC Open Date & Time	10 SEP 2020 11:54
PC Close Date & Time	10 SEP 2020 14:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 19:49
PC Open Date & Time	10 SEP 2020 15:19
PC Close Date & Time	11 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:33
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:16
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:41
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 09:41
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:30
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:39
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

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) _____

US3372060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 OCT 2020

Collection time (00:00-23:59)

10:16 (24 HR)

Collection date and time (derived)

02 OCT 2020 10:16

US3372060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:52

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 OCT 2020 15:20:49
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 16:14:52

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

23 OCT 2020 09:19:16

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

05 NOV 2020 19:58:53

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 99

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 22:17:18

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 17:57:49
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 12:19:07

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 10:46:20

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 09:35:24

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 11:53:55

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 15:55:25

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

03 JAN 2021 12:24:22

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 20:39:53

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 11:30:40

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 11:57:16

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 12:37:15

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 10:02:54

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 06:39:08

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 06:36:23

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

01 MAR 2021 21:04:56

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 17:26:16

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 23:35:07

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 19:34:28

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 09:25:10

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 06:04:50

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 18:12:37

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

20 APR 2021 10:03:30

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Date and time of submission

25 APR 2021 00:28:46

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Date and time of submission

03 MAY 2021 16:06:21

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	31 OCT 2021 00:01
Patient Cloud Close Date & Time	04 NOV 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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°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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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°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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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°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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3372060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:11:41

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 18:49:23

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:51

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Mar 2021 19:59:40

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 17:48:43

Generated On: 09 Jun 2021 17:11:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 20:07:50

Generated On: 09 Jun 2021 17:11:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	09:27 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 09:27
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 17:48:43

Generated On: 09 Jun 2021 17:11:41

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.

US3372060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 15:55:40

Generated On: 09 Jun 2021 17:11:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	09:58 (24 HR)
Collection date and time (derived)	16 MAR 2021 09:58

US3372060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 17:48:43

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 16:44:21

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:44:21

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372060

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:11:41

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"/>

US3372060

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:11:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372060

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

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

Visit date (dd MMM yyyy)	22 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3372060

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 16:26:01

Generated On: 09 Jun 2021 17:11:41

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3372060

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 21:46:19

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

US3372060

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 14:06
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 16:00
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

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.

US3372060

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 15:30 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 15:30

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

US3372060

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

14:17 (24 HR)

Collection date and time (derived)

22 JAN 2021 14:17

US3372060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	14:16
Collection Date and Time (derived)	22 JAN 2021 14:16

US3372060

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

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

US3372060

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3372060

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 13:16
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 14:00
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

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.

US3372060

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 16 FEB 2021

What was the treatment time? (00:00-23:59) 13:35 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 13:35

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

US3372060

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 17:48:43

Generated On: 09 Jun 2021 17:11:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Mar 2021 17:48:43

Generated On: 09 Jun 2021 17:11:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:27 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 09:27
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372060

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 17:48:43

Generated On: 09 Jun 2021 17:11:41

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.

US3372060

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 17:48:43

Generated On: 09 Jun 2021 17:11:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	09:58 (24 HR)
Collection date and time (derived)	16 MAR 2021 09:58

US3372060

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 16:26:10

Generated On: 09 Jun 2021 17:11:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

AEID	USA-US056-2020-MRNA-1273-P30 1000004
Adverse event	RIGHT HIP TRAUMA
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 AUG 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)	16 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	16 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 21:46:19

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	AFTER A BICYCLE-MOTOR VEHICLE ACCIDENT WENT TO DELRAY MEDICAL CENTER FROM 08/14/2020 TO 08/16/2020 WITH RIGHT HIP AND RIGHT KNEE TRAUMA
Serious Adverse Event Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 21:46:19

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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 (2)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

AEID	USA-US056-2020-MRNA-1273-P30 1000004
Adverse event	RIGHT KNEE TRAUMA
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 AUG 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)	04 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	16 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	AFTER A BICYCLE-MOTOR VEHICLE ACCIDENT WENT TO DELRAY MEDICAL CENTER FROM 08/14/2020 TO 08/16/2020 WITH RIGHT HIP AND RIGHT KNEE TRAUMA
Serious Adverse Event Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 21:46:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

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

Yes ☒

No ☐

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE PAIN

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:25:10

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Name of Medication OXYCONTIN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE PAIN

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 22:25:10

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2019
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK PAIN

Dose per administration 100

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) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication OXYCONTIN

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK PAIN

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☒
No ☐

Indication RIGHT KNEE TRAUMA
LACERATION INFECTION
PREVENTION

Dose per administration 100

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 (8)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	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)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 22:25:10

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Name of Medication PANCRELIPASE

Prophylaxis Yes ☐
No ☒

Indication PANCREATIC ENZYME
REPLACEMENT

Dose per administration 36000

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 (10)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	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)		15 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 22:25:10

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Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE PAIN

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	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)	15 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	15 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication PERCOCET 5/325

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE LACERATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication IOPAMIDOL

Prophylaxis Yes ☐
No ☒

Indication RADIOPAQUE CONTRAST AGENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	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)		14 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

Name of Medication ADACEL (TDAP)

Prophylaxis Yes ☒
No ☐

Indication TETANUS
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 22:25:10

Generated On: 09 Jun 2021 17:11:41

	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)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	14 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Feb 2021 16:26:11

Generated On: 09 Jun 2021 17:11:41

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 AUG 2020	CAT SCAN OF THE ABDOMEN	Adverse Event	
14 AUG 2020	CAT SCAN OF THE CERVICAL SPINE	Adverse Event	
14 AUG 2020	X-RAY OF RIGHT KNEE	Adverse Event	

US3372060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:11:41

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:11:41

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 ☐

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

SAEID	USA-US056-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

SAEID	USA-US056-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/OCT/2020 08:32
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

SAEID	USA-US056-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/OCT/2020 14:03
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

SAEID	USA-US056-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/NOV/2020 20:53
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

SAEID	USA-US056-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/NOV/2020 17:55
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

SAEID	USA-US056-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/NOV/2020 18:04
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

SAEID	USA-US056-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/DEC/2020 13:52
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Feb 2021 21:46:19

Generated On: 09 Jun 2021 17:11:41

SAEID	USA-US056-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/FEB/2021 13:53
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

US3372060 (Prod: Palm Beach Research Center)

US3372060

Form: Participant Creation

Generated On: 09 Jun 2021 17:11:41

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'US3372060'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:39:55

US3372060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:38

US3372060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:39:56

US3372060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:38

US3372060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'SCRN'	System	07 Aug 2020 14:34:38

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered (b) (6) 1960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:39:57

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '60'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'YEARS'	System	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '60'	System	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	10 Nov 2020 17:39:55
User entered '7 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Aug 2020'	System	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2020'	System	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:39:56

US3372060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'I'	System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:11:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:25:00

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:29:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:29:14
Data point term sent to Coder	System	11 Aug 2020 20:28:15
User entered 'torn meniscus right knee'	Peter Jacob (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un Apr 1996'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un Apr 1996'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Apr 1996'	System	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '1996'	System	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Apr 1996'	System	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '1996'	System	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Arthroplasty of knee - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:04:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:04:16
Data point term sent to Coder	System	11 Aug 2020 20:28:16
User entered 'arthroplasty right knee'	Peter Jacob (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un Apr 1996'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un Apr 1996'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Apr 1996'	System	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '1996'	System	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Apr 1996'	System	11 Aug 2020 20:28:01

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '1996'	System	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:30:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:30:15
Data point term sent to Coder	System	11 Aug 2020 20:29:19
User entered 'coronary artery disease'	Peter Jacob (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un Sep 2014'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un Sep 2014'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Sep 2014'	System	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2014'	System	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Sep 2014'	System	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2014'	System	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary angioplasty, LLT: Coronary angioplasty - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:23:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:23:16
Data point term sent to Coder	System	11 Aug 2020 20:30:22
User entered 'coronary artery angioplasty'	Peter Jacob (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'UN Sep 2014' reason for change: Data Entry Error	(b) (4)	05 Oct 2020 20:11:49
User entered 'un UNK 2014'	Peter Jacob (b) (4)	11 Aug 2020 20:29:26
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	Peter Jacob (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, the condition on MH# 3 has a stop date of UN SEP 2014. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 08:46:53
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, the condition on MH# 3 has a stop date of UN SEP 2014. Please correct dates or provide explanation for the Med History duration. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:11:54
User entered 'UN Sep 2014' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:11:49
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, the condition on MH# 3 has a stop date of UN SEP 2014. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:37:54
User entered 'un UNK 2014'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Sep 2014'	System	05 Oct 2020 20:11:49
User entered 'Jan 2014'	System	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2014'	System	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Sep 2014'	System	05 Oct 2020 20:11:49
User entered 'Jan 2014'	System	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2014'	System	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Head injury, LLT: Head injury - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 12:29:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 12:29:21
Data point term sent to Coder	System	11 Aug 2020 20:31:26
User entered 'head trauma'	Peter Jacob (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un Sep 2018'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un Sep 2018'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Sep 2018'	System	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2018'	System	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Sep 2018'	System	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2018'	System	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:56:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:56:21
Data point term sent to Coder	System	06 Oct 2020 16:54:56
User entered 'insomnia'	Peter Jacob (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Jan 2017'	System	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2017'	System	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered empty.	System	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered empty.	System	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:58:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:58:18
Data point term sent to Coder	System	06 Oct 2020 16:56:59
User entered 'bilateral knee pain'	Peter Jacob (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Jan 2018'	System	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2018'	System	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered empty.	System	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered empty.	System	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:58:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:58:17
Data point term sent to Coder	System	06 Oct 2020 16:56:59
User entered 'chronic lower back pain'	Peter Jacob (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Jan 2018'	System	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2018'	System	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered empty.	System	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered empty.	System	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis chronic, LLT: Chronic pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 19:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 19:37:58
Data point term sent to Coder	System	19 Feb 2021 19:37:08
User entered 'Chronic Pancreatitis'	(b) (4), (b) (6)	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'Jan 2014'	System	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '2014'	System	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered empty.	System	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered empty.	System	19 Feb 2021 19:36:31

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '07 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10:30'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered '07 Aug 2020 10:30'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '169.9' cm	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 21:31:25
DataPoint set to visible.	(b) (4) System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '82' kg	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 21:31:25
DataPoint set to visible.	(b) (4) System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
Amendment Manager: User entered '28.40711'	System	16 Sep 2020 23:46:56
User entered '28.4'	System	11 Aug 2020 21:31:25
DataPoint set to visible.	System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'kg/m2'	System	11 Aug 2020 21:31:25
DataPoint set to visible.	System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:17:12
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:39:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:38:33
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:36:31
User entered '36.8' C	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:38:33
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25
	(b) (4)	

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:38:33
User entered '74'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25
	(b) (4)	

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'bpm'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:38:33
User entered '16'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25
	(b) (4)	

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'breaths/min'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:38:33
User entered '116'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25
	(b) (4)	

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'mmHg'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:38:33
User entered '83'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25
	(b) (4)	

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User entered 'mmHg'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 00:27:12

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12

US3372060

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 21:34:24

US3372060

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
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)	11 Sep 2020 22:16:43
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:42:51
User entered '07 Aug 2020'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:34:24

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

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 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:27:12
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 21:34:48

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '07 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:34:48

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[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 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Clinic (Clinic)'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:34:48

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'VISIT1'	System	11 Aug 2020 21:34:48

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:01
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:45:05

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:41

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:01
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:47:32
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:47:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 15:45:05
User entered '101380' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:45:05

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:41

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:01
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:45:05

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:41

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 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:41

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 Apr 2021 01:03:08
User closed query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 08:26:57
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:01
Query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' answered with 'DCF has already been submitted' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 20:44:17
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:49:55
Query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	26 Mar 2021 15:49:47
Comment added 'dcf submitted'.	Mary Sergalis (b) (4)	19 Nov 2020 20:30:56
Comment added 'DCF submitted to endpoint to correct stratification'.	Mary Sergalis (b) (4)	10 Nov 2020 18:31:12
Comment added 'dcf SUBMITTED FOR CORRECTION ON 07-NOV-2020'.	Mary Sergalis (b) (4)	07 Nov 2020 15:59:19
Comment added 'Unable to update to correct at risk status'.	Mary Sergalis (b) (4)	22 Oct 2020 13:32:25
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	07 Aug 2020 15:54:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:41

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:41

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:17:09
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:51:45
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:51:26
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:36:23
User entered '169.9' cm	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:51:26
User entered '82' kg	Peter Jacob (b) (4)	11 Aug 2020 21:39:45
	(b) (4)	

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:17:09
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:51:45
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:51:26
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:36:23
User entered '169.9' cm	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:51:26
User entered '82' kg	Peter Jacob (b) (4)	11 Aug 2020 21:39:45
	(b) (4)	

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '07 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10:30'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered '07 Aug 2020 10:30'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '36.8' C	(b) (4) Peter Jacob (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '74'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'bpm'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'breaths/min'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '116'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'mmHg'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '83'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'mmHg'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:17:09
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:51:45
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:51:26
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:36:23
User entered '169.9' cm	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:51:26
User entered '82' kg	Peter Jacob (b) (4)	11 Aug 2020 21:39:45
	(b) (4)	

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '07 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 05:09:13
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post-dose vital signs must be collected at least 30 minutes after dose time' (Site from System).	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:43:02
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).		11 Aug 2020 21:41:41
User entered '12:52'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered '07 Aug 2020 12:52'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '36.7' C	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '69'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'bpm'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'breaths/min'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '121'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'mmHg'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '85'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'mmHg'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:43:08

US3372060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '07 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:43:08

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '7 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '12:13'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered '7 Aug 2020 12:13'	System	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'ONCE'	System	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
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	26 Aug 2020 18:53:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4)	26 Aug 2020 18:53:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	07 Aug 2020 16:33:11
	(b) (4), (b) (6)	07 Aug 2020 16:33:11

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '7 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:33:11

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '11:19'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:33:11

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered '7 Aug 2020 11:19'	System	07 Aug 2020 16:33:11

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '7 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '11:17'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered '7 Aug 2020 11:17'	System	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 18:44:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 18:44:12
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	26 Aug 2020 18:44:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Aug 2020 16:32:48
User entered empty.	System	07 Aug 2020 16:32:48
	(b) (4), (b) (6)	

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered empty.	System	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	11 Aug 2020 22:16:39

US3372060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'I'	System	11 Aug 2020 22:16:39

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:49:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '606058d1-8220-4c78-aa48-f8d1b7377595'	System	07 Aug 2020 16:51:18
User entered 'Yes (Y)'	System	07 Aug 2020 16:51:18

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:50:45', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '606058d1-8220-4c78-aa48-f8d1b7377595'	System	07 Aug 2020 16:51:18
User entered '98.2'	System	07 Aug 2020 16:51:18

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:51:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '606058d1-8220-4c78-aa48-f8d1b7377595'	System	07 Aug 2020 16:51:18
User entered 'No (N)'	System	07 Aug 2020 16:51:18

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:51:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '606058d1-8220-4c78-aa48-f8d1b7377595'	System	07 Aug 2020 16:51:18
User entered '07 Aug 2020 12:51'	System	07 Aug 2020 16:51:18

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 12:33'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 15:03'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5db7a8da-43ac-4ace-88b5-fbd7e0b14ae4'	System	08 Aug 2020 01:24:50
User entered 'Yes (Y)'	System	08 Aug 2020 01:24:50

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:29', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5db7a8da-43ac-4ace-88b5-fbd7e0b14ae4'	System	08 Aug 2020 01:24:50
User entered '97.2'	System	08 Aug 2020 01:24:50

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5db7a8da-43ac-4ace-88b5-fbd7e0b14ae4'	System	08 Aug 2020 01:24:50
User entered 'No (N)'	System	08 Aug 2020 01:24:50

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5db7a8da-43ac-4ace-88b5-fbd7e0b14ae4'	System	08 Aug 2020 01:24:50
User entered '07 Aug 2020 21:24'	System	08 Aug 2020 01:24:50

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 15:58'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 2'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7dadebca-6510-4667-8d23-75c8a4bfd39b'	System	08 Aug 2020 22:41:25
User entered 'Yes (Y)'	System	08 Aug 2020 22:41:25

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:16', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7dadebca-6510-4667-8d23-75c8a4bfd39b'	System	08 Aug 2020 22:41:25
User entered '98.2'	System	08 Aug 2020 22:41:25

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7dadebca-6510-4667-8d23-75c8a4bfd39b'	System	08 Aug 2020 22:41:25
User entered 'No (N)'	System	08 Aug 2020 22:41:25

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:23', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7dadebca-6510-4667-8d23-75c8a4bfd39b'	System	08 Aug 2020 22:41:25
User entered '08 Aug 2020 18:41'	System	08 Aug 2020 22:41:25

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 3'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '92167933-829e-4a82-a0c4-c1e1de9993c3'	System	09 Aug 2020 23:20:52
User entered 'Yes (Y)'	System	09 Aug 2020 23:20:52

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '92167933-829e-4a82-a0c4-c1e1de9993c3' User entered '98.7'	System	09 Aug 2020 23:20:52
	System	09 Aug 2020 23:20:52

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:46', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '92167933-829e-4a82-a0c4-c1e1de9993c3'	System	09 Aug 2020 23:20:52
User entered 'No (N)'	System	09 Aug 2020 23:20:52

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '92167933-829e-4a82-a0c4-c1e1de9993c3'	System	09 Aug 2020 23:20:52
User entered '09 Aug 2020 19:20'	System	09 Aug 2020 23:20:52

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 4'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:27:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c87748ec-06f6-4055-bdda-96094bfe3fc4'	System	11 Aug 2020 02:28:07
User entered 'Yes (Y)'	System	11 Aug 2020 02:28:07

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:27:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c87748ec-06f6-4055-bdda-96094bfe3fc4'	System	11 Aug 2020 02:28:07
User entered '97.3'	System	11 Aug 2020 02:28:07

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:27:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c87748ec-06f6-4055-bdda-96094bfe3fc4'	System	11 Aug 2020 02:28:07
User entered 'No (N)'	System	11 Aug 2020 02:28:07

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c87748ec-06f6-4055-bdda-96094bfe3fc4'	System	11 Aug 2020 02:28:07
User entered '10 Aug 2020 22:28'	System	11 Aug 2020 02:28:07

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 5'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '622691f9-b859-4983-aa38-9c34dfc2725f'	System	12 Aug 2020 00:45:20
User entered 'Yes (Y)'	System	12 Aug 2020 00:45:20

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:09', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '622691f9-b859-4983-aa38-9c34dfc2725f' User entered '98.1'	System	12 Aug 2020 00:45:20
	System	12 Aug 2020 00:45:20

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '622691f9-b859-4983-aa38-9c34dfc2725f'	System	12 Aug 2020 00:45:20
User entered 'No (N)'	System	12 Aug 2020 00:45:20

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '622691f9-b859-4983-aa38-9c34dfc2725f'	System	12 Aug 2020 00:45:20
User entered '11 Aug 2020 20:45'	System	12 Aug 2020 00:45:20

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 6'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '11d30afa-04a4-41b2-866f-5d5a2253eea7'	System	12 Aug 2020 23:21:27
User entered 'Yes (Y)'	System	12 Aug 2020 23:21:27

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '11d30afa-04a4-41b2-866f-5d5a2253eea7'	System	12 Aug 2020 23:21:27
User entered '98.6'	System	12 Aug 2020 23:21:27

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '11d30afa-04a4-41b2-866f-5d5a2253eea7'	System	12 Aug 2020 23:21:27
User entered 'No (N)'	System	12 Aug 2020 23:21:27

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '11d30afa-04a4-41b2-866f-5d5a2253eea7'	System	12 Aug 2020 23:21:27
User entered '12 Aug 2020 19:21'	System	12 Aug 2020 23:21:27

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 7'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:11:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b7e24ad2-3939-4d84-bb82-08cef967ec5d'	System	14 Aug 2020 01:12:03
User entered 'Yes (Y)'	System	14 Aug 2020 01:12:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:11:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b7e24ad2-3939-4d84-bb82-08cef967ec5d' User entered '98.9'	System	14 Aug 2020 01:12:03
	System	14 Aug 2020 01:12:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:11:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b7e24ad2-3939-4d84-bb82-08cef967ec5d'	System	14 Aug 2020 01:12:03
User entered 'No (N)'	System	14 Aug 2020 01:12:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b7e24ad2-3939-4d84-bb82-08cef967ec5d'	System	14 Aug 2020 01:12:03
User entered '13 Aug 2020 21:12'	System	14 Aug 2020 01:12:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:52:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered 'None (1)'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:52:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered 'No (N)'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered 'No (N)'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered 'None (1)'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered '07 Aug 2020 12:53'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 12:33'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 15:03'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered 'None (1)'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:25:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered 'No (N)'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:25:43', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered 'No (N)'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:25:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered 'None (1)'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:25:54', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered '07 Aug 2020 21:25'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 15:58'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 2'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered 'None (1)'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered 'No (N)'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered 'No (N)'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered 'None (1)'	System	08 Aug 2020 22:41:45

b

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered '08 Aug 2020 18:41'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 3'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered 'None (1)'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:56', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered 'No (N)'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered 'No (N)'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered 'None (1)'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered '09 Aug 2020 19:21'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 4'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered 'None (1)'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered 'No (N)'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered 'No (N)'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:19', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered 'None (1)'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered '10 Aug 2020 22:28'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 5'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered 'None (1)'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered 'No (N)'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:29', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered 'No (N)'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:35', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered 'None (1)'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered '11 Aug 2020 20:45'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 6'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:30', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaaece-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered 'None (1)'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaaece-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered 'No (N)'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaaece-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered 'No (N)'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaaece-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered 'None (1)'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaaece-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered '12 Aug 2020 19:21'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 7'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered 'None (1)'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered 'No (N)'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered 'No (N)'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered 'None (1)'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered '13 Aug 2020 21:12'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:29', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'No (N)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered '07 Aug 2020 12:53'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 12:33'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 15:03'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:19', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'No (N)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:35', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered '07 Aug 2020 21:26'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '07 Aug 2020 15:58'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 2'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:03', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'No (N)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:12', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered '08 Aug 2020 18:42'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 3'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:09', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'No (N)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered '09 Aug 2020 19:21'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 4'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'No (N)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered '10 Aug 2020 22:28'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 5'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:46', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:46:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:46:09', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'No (N)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:46:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered '11 Aug 2020 20:46'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 6'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:52', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:54', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:56', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:58', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:22:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'No (N)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:22:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered '12 Aug 2020 19:22'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 7'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'No (N)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered '13 Aug 2020 21:12'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	26 Aug 2020 15:16:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '17 Aug 2020'	(b) (4) Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 15:16:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 15:16:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	Alexandra Arango (b) (4)	26 Aug 2020 15:16:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	21 Aug 2020 20:28:57

US3372060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'I'	System	21 Aug 2020 20:28:57

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	21 Aug 2020 20:29:09

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered '21 Aug 2020'	(b) (4) Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 20:29:09

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 20:29:09

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered empty.	Alexandra Arango (b) (4)	21 Aug 2020 20:29:09

US3372060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	21 Aug 2020 20:29:15

US3372060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'I'	System	21 Aug 2020 20:29:15

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	03 Sep 2020 18:08:11

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered '31 Aug 2020'	(b) (4) Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 18:08:11

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 18:08:11

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered empty.	Alexandra Arango (b) (4)	03 Sep 2020 18:08:11

US3372060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 18:08:16

US3372060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:03:08
User entered 'I'	System	03 Sep 2020 18:08:16

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:42:51

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:42:51

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:42:51

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'VISIT2'	System	10 Sep 2020 15:42:51

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10:34'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered '10 Sep 2020 10:34'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '36.8' C	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '77'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'bpm'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '14'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'breaths/min'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '119'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'mmHg'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '74'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'mmHg'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '12:11'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered '10 Sep 2020 12:11'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '36.7' C	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '83'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'bpm'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '14'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'breaths/min'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '127'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'mmHg'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '84' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	15 Sep 2020 16:31:22
User entered '74'	(b) (4)	
	Peter Jacob (b) (4)	15 Sep 2020 16:31:18
	(b) (4)	

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'mmHg'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:30

US3372060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:30

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

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)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '11:34'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered '10 Sep 2020 11:34'	System	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'ONCE'	System	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:41

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10 Sep 2020'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:41

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10:58'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:41

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered '10 Sep 2020 10:58'	System	15 Sep 2020 16:31:41

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10 Sep 2020'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:41

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10:57'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered '10 Sep 2020 10:57'	System	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered empty.	System	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	10 Sep 2020 17:17:28

US3372060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'I'	System	10 Sep 2020 17:17:28

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:10:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3613aa70-6268-4bb9-9e7b-07f97a95a8b5'	System	10 Sep 2020 16:10:43
User entered 'Yes (Y)'	System	10 Sep 2020 16:10:43

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:10:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3613aa70-6268-4bb9-9e7b-07f97a95a8b5' User entered '98.1'	System	10 Sep 2020 16:10:43
	System	10 Sep 2020 16:10:43

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:10:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3613aa70-6268-4bb9-9e7b-07f97a95a8b5'	System	10 Sep 2020 16:10:43
User entered 'No (N)'	System	10 Sep 2020 16:10:43

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:10:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3613aa70-6268-4bb9-9e7b-07f97a95a8b5'	System	10 Sep 2020 16:10:43
User entered '10 Sep 2020 12:10'	System	10 Sep 2020 16:10:43

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 11:54'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 14:24'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:47:29', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ae0b690d-0698-4d1e-bae5-2dde12024496'	System	10 Sep 2020 23:48:09
User entered 'Yes (Y)'	System	10 Sep 2020 23:48:09

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:47:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ae0b690d-0698-4d1e-bae5-2dde12024496'	System	10 Sep 2020 23:48:09
User entered '98.3'	System	10 Sep 2020 23:48:09

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ae0b690d-0698-4d1e-bae5-2dde12024496'	System	10 Sep 2020 23:48:09
User entered 'No (N)'	System	10 Sep 2020 23:48:09

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ae0b690d-0698-4d1e-bae5-2dde12024496'	System	10 Sep 2020 23:48:09
User entered '10 Sep 2020 19:48'	System	10 Sep 2020 23:48:09

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 15:19'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 2'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '517260d8-9acc-447e-84ab-081d76b3eebd'	System	11 Sep 2020 22:32:55
User entered 'Yes (Y)'	System	11 Sep 2020 22:32:55

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '517260d8-9acc-447e-84ab-081d76b3eebd'	System	11 Sep 2020 22:32:55
User entered '98.8'	System	11 Sep 2020 22:32:55

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '517260d8-9acc-447e-84ab-081d76b3eebd'	System	11 Sep 2020 22:32:55
User entered 'No (N)'	System	11 Sep 2020 22:32:55

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '517260d8-9acc-447e-84ab-081d76b3eebd'	System	11 Sep 2020 22:32:55
User entered '11 Sep 2020 18:32'	System	11 Sep 2020 22:32:55

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 3'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0c6f7569-5eba-4730-b852-7a9dae61a16f'	System	13 Sep 2020 02:15:58
User entered 'Yes (Y)'	System	13 Sep 2020 02:15:58

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0c6f7569-5eba-4730-b852-7a9dae61a16f' User entered '98.3'	System	13 Sep 2020 02:15:58
	System	13 Sep 2020 02:15:58

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0c6f7569-5eba-4730-b852-7a9dae61a16f'	System	13 Sep 2020 02:15:58
User entered 'No (N)'	System	13 Sep 2020 02:15:58

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0c6f7569-5eba-4730-b852-7a9dae61a16f'	System	13 Sep 2020 02:15:58
User entered '12 Sep 2020 22:15'	System	13 Sep 2020 02:15:58

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 4'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:40:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'eeb9f6e7-1583-445e-9c39-0955ae1f54d9'	System	14 Sep 2020 02:40:47
User entered 'Yes (Y)'	System	14 Sep 2020 02:40:47

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:40:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'eeb9f6e7-1583-445e-9c39-0955ae1f54d9'	System	14 Sep 2020 02:40:47
User entered '97.0'	System	14 Sep 2020 02:40:47

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:40:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'eeb9f6e7-1583-445e-9c39-0955ae1f54d9'	System	14 Sep 2020 02:40:47
User entered 'No (N)'	System	14 Sep 2020 02:40:47

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:40:45', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'eeb9f6e7-1583-445e-9c39-0955ae1f54d9'	System	14 Sep 2020 02:40:47
User entered '13 Sep 2020 22:40'	System	14 Sep 2020 02:40:47

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 5'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e7b29902-efd8-48f7-9417-a2dbd485d60f'	System	15 Sep 2020 13:38:40
User entered 'Yes (Y)'	System	15 Sep 2020 13:38:40

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e7b29902-efd8-48f7-9417-a2dbd485d60f'	System	15 Sep 2020 13:38:40
User entered '98.5'	System	15 Sep 2020 13:38:40

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e7b29902-efd8-48f7-9417-a2dbd485d60f'	System	15 Sep 2020 13:38:40
User entered 'No (N)'	System	15 Sep 2020 13:38:40

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e7b29902-efd8-48f7-9417-a2dbd485d60f'	System	15 Sep 2020 13:38:40
User entered '15 Sep 2020 09:38'	System	15 Sep 2020 13:38:40

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 6'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8e650f9-25de-4cbc-885d-ba0b0d65182b'	System	16 Sep 2020 01:29:34
User entered 'Yes (Y)'	System	16 Sep 2020 01:29:34

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8e650f9-25de-4cbc-885d-ba0b0d65182b'	System	16 Sep 2020 01:29:34
User entered '94.3'	System	16 Sep 2020 01:29:34

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8e650f9-25de-4cbc-885d-ba0b0d65182b'	System	16 Sep 2020 01:29:34
User entered 'No (N)'	System	16 Sep 2020 01:29:34

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8e650f9-25de-4cbc-885d-ba0b0d65182b'	System	16 Sep 2020 01:29:34
User entered '15 Sep 2020 21:29'	System	16 Sep 2020 01:29:34

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 7'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:16', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5d843dd6-c1fc-4e59-8967-e57cd6479d4e'	System	17 Sep 2020 00:38:33
User entered 'Yes (Y)'	System	17 Sep 2020 00:38:33

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5d843dd6-c1fc-4e59-8967-e57cd6479d4e'	System	17 Sep 2020 00:38:33
User entered '99.3'	System	17 Sep 2020 00:38:33

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5d843dd6-c1fc-4e59-8967-e57cd6479d4e'	System	17 Sep 2020 00:38:33
User entered 'No (N)'	System	17 Sep 2020 00:38:33

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5d843dd6-c1fc-4e59-8967-e57cd6479d4e'	System	17 Sep 2020 00:38:33
User entered '16 Sep 2020 20:38'	System	17 Sep 2020 00:38:33

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered 'None (1)'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered 'No (N)'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered 'No (N)'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered 'None (1)'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered '10 Sep 2020 12:11'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 11:54'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 14:24'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:23', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered 'None (1)'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered 'No (N)'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:30', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered 'No (N)'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered 'None (1)'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered '10 Sep 2020 19:48'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 15:19'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 2'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:32', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered 'None (1)'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered 'No (N)'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered 'No (N)'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered 'None (1)'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered '11 Sep 2020 18:32'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 3'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:14:50', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered 'None (1)'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:14:57', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered 'No (N)'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered 'No (N)'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:09', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered 'None (1)'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f' User entered '12 Sep 2020 22:15'	System	13 Sep 2020 02:15:49
	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 4'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered 'None (1)'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered 'No (N)'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered 'No (N)'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered 'None (1)'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 5'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:46', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered 'None (1)'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered 'No (N)'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered 'No (N)'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered 'None (1)'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered '15 Sep 2020 09:38'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 6'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered 'None (1)'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:43', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered 'No (N)'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered 'No (N)'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered 'None (1)'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered '15 Sep 2020 21:30'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 7'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered 'None (1)'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered 'No (N)'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered 'No (N)'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:54', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered 'None (1)'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:56', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered '16 Sep 2020 20:38'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:30', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a' User entered 'None (0)'	System	10 Sep 2020 16:11:47
	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a' User entered 'None (0)'	System	10 Sep 2020 16:11:47
	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:39', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:43', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'No (N)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:45', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered '10 Sep 2020 12:11'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 11:54'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 14:24'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:01', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'No (N)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered '10 Sep 2020 19:49'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '10 Sep 2020 15:19'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 2'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:56', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:12', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'No (N)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered '11 Sep 2020 18:33'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 3'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:52', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:57', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:01', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b' User entered 'None (0)'	System	13 Sep 2020 02:16:15
	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'No (N)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered '12 Sep 2020 22:16'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 4'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'No (N)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 5'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:01', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:03', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'No (N)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:41:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered '15 Sep 2020 09:41'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 6'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'No (N)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered '15 Sep 2020 21:30'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 7'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:03', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:06', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:12', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

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 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'No (N)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered '16 Sep 2020 20:39'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 17:47:12

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 07:23:55
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit was completed within window per protocol.' (Site from System).	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:47:21
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Sep 2020 17:47:12
User entered '11 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:47:12

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 17:47:12

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 17:47:12

US3372060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 17:48:22

US3372060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'I'	System	21 Sep 2020 17:48:22

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 17:51:35

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 05:42:54
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit was completed within window per protocol.' (Site from System).	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:52:35
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Sep 2020 17:51:35
User entered '18 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:51:35

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 17:51:35

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 17:51:35
	(b) (4)	

US3372060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 17:52:41

US3372060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'I'	System	21 Sep 2020 17:52:41

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	28 Sep 2020 13:06:40

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 11:36:20
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol' (Site from System).	Alexandra Arango (b) (4) (b) (4)	28 Sep 2020 13:07:34
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Sep 2020 13:06:40
User entered '26 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	28 Sep 2020 13:06:40

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	28 Sep 2020 13:06:40

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Alexandra Arango (b) (4)	28 Sep 2020 13:06:40

US3372060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	28 Sep 2020 13:07:38

US3372060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'I'	System	28 Sep 2020 13:07:38

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Elena Acosta (b) (4) (b) (4)	02 Oct 2020 13:56:01

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 10:43:24
User entered '02 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 23:02:34
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'data correct as is' (Site from System).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 23:02:10
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Oct 2020 13:56:01
User entered '2 Oct 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 13:56:01

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Clinic (Clinic)'	(b) (4) Elena Acosta (b) (4) (b) (4)	02 Oct 2020 13:56:01

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'VISIT3'	System	02 Oct 2020 13:56:01

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27

US3372060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:15

US3372060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '02 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:15

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	05 Oct 2020 20:12:23

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '02 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:23

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '10:16'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:23

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered '02 Oct 2020 10:16'	System	05 Oct 2020 20:12:23

US3372060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:27

US3372060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'I'	System	05 Oct 2020 20:12:27

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 64'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-07T15:20:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '4319b4b5-4518-4b7d-b2f2-3d5d1ce7a637'	System	07 Oct 2020 19:20:53
User entered 'No (N)'	System	07 Oct 2020 19:20:53

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-07T15:20:45', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '4319b4b5-4518-4b7d-b2f2-3d5d1ce7a637'	System	07 Oct 2020 19:20:53
User entered 'No (N)'	System	07 Oct 2020 19:20:53

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-07T15:20:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '4319b4b5-4518-4b7d-b2f2-3d5d1ce7a637'	System	07 Oct 2020 19:20:53
User entered '07 Oct 2020 15:20:49'	System	07 Oct 2020 19:20:53

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 71'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-16T16:14:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3a9b9bfe-2bee-434a-b662-64a888cede71'	System	16 Oct 2020 20:14:55
User entered 'No (N)'	System	16 Oct 2020 20:14:55

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-16T16:14:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3a9b9bfe-2bee-434a-b662-64a888cede71'	System	16 Oct 2020 20:14:55
User entered 'No (N)'	System	16 Oct 2020 20:14:55

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-16T16:14:52', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3a9b9bfe-2bee-434a-b662-64a888cede71' User entered '16 Oct 2020 16:14:52'	System	16 Oct 2020 20:14:55
	System	16 Oct 2020 20:14:55

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 78'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-23T09:19:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e95081ab-0518-443b-988a-5b532b3d91e6'	System	23 Oct 2020 13:19:23
User entered 'No (N)'	System	23 Oct 2020 13:19:23

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-23T09:19:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e95081ab-0518-443b-988a-5b532b3d91e6'	System	23 Oct 2020 13:19:23
User entered 'No (N)'	System	23 Oct 2020 13:19:23

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-23T09:19:16', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e95081ab-0518-443b-988a-5b532b3d91e6' User entered '23 Oct 2020 09:19:16'	System	23 Oct 2020 13:19:23
	System	23 Oct 2020 13:19:23

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 92'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-05T19:58:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '56dfc630-cfa8-4620-b13a-761b77f0af8b'	System	06 Nov 2020 00:58:57
User entered 'No (N)'	System	06 Nov 2020 00:58:57

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-05T19:58:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '56dfc630-cfa8-4620-b13a-761b77f0af8b'	System	06 Nov 2020 00:58:57
User entered 'No (N)'	System	06 Nov 2020 00:58:57

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-05T19:58:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '56dfc630-cfa8-4620-b13a-761b77f0af8b'	System	06 Nov 2020 00:58:57
User entered '05 Nov 2020 19:58:53'	System	06 Nov 2020 00:58:57

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 99'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-15T22:17:06', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0e4a1813-d8e3-4351-9c01-40fd5efffe8e'	System	16 Nov 2020 03:17:22
User entered 'No (N)'	System	16 Nov 2020 03:17:22

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-15T22:17:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0e4a1813-d8e3-4351-9c01-40fd5efffe8e'	System	16 Nov 2020 03:17:22
User entered 'No (N)'	System	16 Nov 2020 03:17:22

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-15T22:17:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0e4a1813-d8e3-4351-9c01-40fd5efffe8e'	System	16 Nov 2020 03:17:22
User entered '15 Nov 2020 22:17:18'	System	16 Nov 2020 03:17:22

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:21:42
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 106'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:37:12
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2020-11-23T17:57:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6b32fdab-90e5-4cd4-ab6d-b0bbf51dff30'	System	23 Nov 2020 22:57:52
User entered 'No (N)'	System	23 Nov 2020 22:57:52

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-11-23T17:57:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6b32fdab-90e5-4cd4-ab6d-b0bbf51dff30'	System	23 Nov 2020 22:57:52
User entered 'No (N)'	System	23 Nov 2020 22:57:52

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-23T17:57:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6b32fdab-90e5-4cd4-ab6d-b0bbf51dff30'	System	23 Nov 2020 22:57:52
User entered '23 Nov 2020 17:57:49'	System	23 Nov 2020 22:57:52

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2020-11-29T12:18:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c3b81607-de3d-4ac5-81df-2184e1d16173'	System	29 Nov 2020 17:19:13
User entered 'No (N)'	System	29 Nov 2020 17:19:13

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-11-29T12:19:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c3b81607-de3d-4ac5-81df-2184e1d16173'	System	29 Nov 2020 17:19:13
User entered 'No (N)'	System	29 Nov 2020 17:19:13

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-29T12:19:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c3b81607-de3d-4ac5-81df-2184e1d16173'	System	29 Nov 2020 17:19:13
User entered '29 Nov 2020 12:19:07'	System	29 Nov 2020 17:19:13

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2020-12-06T10:46:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '14841f5c-c387-45eb-b03f-bdc9846ac861'	System	06 Dec 2020 15:46:21
User entered 'No (N)'	System	06 Dec 2020 15:46:21

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-12-06T10:46:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '14841f5c-c387-45eb-b03f-bdc9846ac861'	System	06 Dec 2020 15:46:21
User entered 'No (N)'	System	06 Dec 2020 15:46:21

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-12-06T10:46:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '14841f5c-c387-45eb-b03f-bdc9846ac861' User entered '06 Dec 2020 10:46:20'	System	06 Dec 2020 15:46:21
	System	06 Dec 2020 15:46:21

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2020-12-14T09:35:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1beda4bf-c69a-479a-b206-8ba6d46e964c'	System	14 Dec 2020 14:35:28
User entered 'No (N)'	System	14 Dec 2020 14:35:28

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-12-14T09:35:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1beda4bf-c69a-479a-b206-8ba6d46e964c'	System	14 Dec 2020 14:35:28
User entered 'No (N)'	System	14 Dec 2020 14:35:28

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-12-14T09:35:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1beda4bf-c69a-479a-b206-8ba6d46e964c'	System	14 Dec 2020 14:35:28
User entered '14 Dec 2020 09:35:24'	System	14 Dec 2020 14:35:28

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2020-12-20T11:53:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e3ff289b-77aa-42a7-9154-b945277884d1'	System	20 Dec 2020 16:53:58
User entered 'No (N)'	System	20 Dec 2020 16:53:58

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-12-20T11:53:52', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e3ff289b-77aa-42a7-9154-b945277884d1'	System	20 Dec 2020 16:53:58
User entered 'No (N)'	System	20 Dec 2020 16:53:58

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-12-20T11:53:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e3ff289b-77aa-42a7-9154-b945277884d1'	System	20 Dec 2020 16:53:58
User entered '20 Dec 2020 11:53:55'	System	20 Dec 2020 16:53:58

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2020-12-29T15:55:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '09ecd68c-182e-4d52-8de1-87e34f993bc4'	System	29 Dec 2020 20:55:27
User entered 'No (N)'	System	29 Dec 2020 20:55:27

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-12-29T15:55:23', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '09ecd68c-182e-4d52-8de1-87e34f993bc4'	System	29 Dec 2020 20:55:27
User entered 'No (N)'	System	29 Dec 2020 20:55:27

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-12-29T15:55:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '09ecd68c-182e-4d52-8de1-87e34f993bc4'	System	29 Dec 2020 20:55:27
User entered '29 Dec 2020 15:55:25'	System	29 Dec 2020 20:55:27

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-01-03T12:24:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dc8b0f56-b8d2-4d99-b80b-9d8fa8a6286c'	System	03 Jan 2021 17:24:21
User entered 'No (N)'	System	03 Jan 2021 17:24:21

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-01-03T12:24:19', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dc8b0f56-b8d2-4d99-b80b-9d8fa8a6286c'	System	03 Jan 2021 17:24:21
User entered 'No (N)'	System	03 Jan 2021 17:24:21

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-01-03T12:24:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dc8b0f56-b8d2-4d99-b80b-9d8fa8a6286c'	System	03 Jan 2021 17:24:21
User entered '03 Jan 2021 12:24:22'	System	03 Jan 2021 17:24:21

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-01-13T20:39:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '60d296d5-08ef-44e6-893d-408e33972bd5'	System	14 Jan 2021 01:39:57
User entered 'No (N)'	System	14 Jan 2021 01:39:57

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-01-13T20:39:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '60d296d5-08ef-44e6-893d-408e33972bd5'	System	14 Jan 2021 01:39:57
User entered 'No (N)'	System	14 Jan 2021 01:39:57

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-01-13T20:39:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '60d296d5-08ef-44e6-893d-408e33972bd5' User entered '13 Jan 2021 20:39:53'	System	14 Jan 2021 01:39:57

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-01-17T11:30:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1aa80cb5-a67a-4c4c-ad6d-b53c0b614763'	System	17 Jan 2021 16:30:44
User entered 'No (N)'	System	17 Jan 2021 16:30:44

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-01-17T11:30:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1aa80cb5-a67a-4c4c-ad6d-b53c0b614763'	System	17 Jan 2021 16:30:44
User entered 'No (N)'	System	17 Jan 2021 16:30:44

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-01-17T11:30:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1aa80cb5-a67a-4c4c-ad6d-b53c0b614763' User entered '17 Jan 2021 11:30:40'	System	17 Jan 2021 16:30:44

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-01-24T11:57:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1bf79555-2f27-42c9-a56c-237cfba7a9a5'	System	24 Jan 2021 16:57:17
User entered 'No (N)'	System	24 Jan 2021 16:57:17

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-01-24T11:57:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1bf79555-2f27-42c9-a56c-237cfba7a9a5'	System	24 Jan 2021 16:57:17
User entered 'No (N)'	System	24 Jan 2021 16:57:17

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-01-24T11:57:16', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '1bf79555-2f27-42c9-a56c-237cfba7a9a5'	System	24 Jan 2021 16:57:17
User entered '24 Jan 2021 11:57:16'	System	24 Jan 2021 16:57:17

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-01-31T12:37:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3bc2e8d9-c975-4706-abe7-a1e18f677d76'	System	31 Jan 2021 17:37:19
User entered 'No (N)'	System	31 Jan 2021 17:37:19

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-01-31T12:37:12', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3bc2e8d9-c975-4706-abe7-a1e18f677d76'	System	31 Jan 2021 17:37:19
User entered 'No (N)'	System	31 Jan 2021 17:37:19

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-01-31T12:37:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3bc2e8d9-c975-4706-abe7-a1e18f677d76'	System	31 Jan 2021 17:37:19
User entered '31 Jan 2021 12:37:15'	System	31 Jan 2021 17:37:19

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-02-07T10:02:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '71d87156-065f-4e17-9052-c7cdb3039e93'	System	07 Feb 2021 15:02:57
User entered 'No (N)'	System	07 Feb 2021 15:02:57

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-02-07T10:02:52', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '71d87156-065f-4e17-9052-c7cdb3039e93'	System	07 Feb 2021 15:02:57
User entered 'No (N)'	System	07 Feb 2021 15:02:57

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-02-07T10:02:54', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '71d87156-065f-4e17-9052-c7cdb3039e93'	System	07 Feb 2021 15:02:57
User entered '07 Feb 2021 10:02:54'	System	07 Feb 2021 15:02:57

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-02-14T06:39:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a284aeb-5925-4092-8360-b24b00e9ee49'	System	14 Feb 2021 11:39:12
User entered 'No (N)'	System	14 Feb 2021 11:39:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-02-14T06:39:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a284aeb-5925-4092-8360-b24b00e9ee49'	System	14 Feb 2021 11:39:12
User entered 'No (N)'	System	14 Feb 2021 11:39:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-02-14T06:39:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a284aeb-5925-4092-8360-b24b00e9ee49'	System	14 Feb 2021 11:39:12
User entered '14 Feb 2021 06:39:08'	System	14 Feb 2021 11:39:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-02-21T06:36:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f46f945-00f0-490b-b932-bb81670be028'	System	21 Feb 2021 11:36:30
User entered 'No (N)'	System	21 Feb 2021 11:36:30

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-02-21T06:36:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f46f945-00f0-490b-b932-bb81670be028'	System	21 Feb 2021 11:36:30
User entered 'No (N)'	System	21 Feb 2021 11:36:30

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-02-21T06:36:23', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f46f945-00f0-490b-b932-bb81670be028'	System	21 Feb 2021 11:36:30
User entered '21 Feb 2021 06:36:23'	System	21 Feb 2021 11:36:30

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-03-01T21:04:44-05:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'db3b5d7d-6bb9-476e-85bf-c50f6e128240'	System	02 Mar 2021 02:15:27
User entered 'No (N)'	System	02 Mar 2021 02:15:27

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-03-01T21:04:52-05:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'db3b5d7d-6bb9-476e-85bf-c50f6e128240'	System	02 Mar 2021 02:15:27
User entered 'No (N)'	System	02 Mar 2021 02:15:27

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-03-01T21:04:56-05:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'db3b5d7d-6bb9-476e-85bf-c50f6e128240'	System	02 Mar 2021 02:15:27
User entered '01 Mar 2021 21:04:56'	System	02 Mar 2021 02:15:27

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-03-10T17:26:08-05:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e448e254-7c8a-48dc-b6b2-d394609c528e' User entered 'No (N)'	System	10 Mar 2021 22:26:19
	System	10 Mar 2021 22:26:19

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-03-10T17:26:13-05:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e448e254-7c8a-48dc-b6b2-d394609c528e'	System	10 Mar 2021 22:26:19
User entered 'No (N)'	System	10 Mar 2021 22:26:19

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-03-10T17:26:16-05:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e448e254-7c8a-48dc-b6b2-d394609c528e' User entered '10 Mar 2021 17:26:16'	System	10 Mar 2021 22:26:19
	System	10 Mar 2021 22:26:19

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-03-15T23:35:01-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0516f293-feff-426b-87da-0e18f83186c1' User entered 'No (N)'	System	16 Mar 2021 03:35:10
	System	16 Mar 2021 03:35:10

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-03-15T23:35:04-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0516f293-feff-426b-87da-0e18f83186c1'	System	16 Mar 2021 03:35:10
User entered 'No (N)'	System	16 Mar 2021 03:35:10

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-03-15T23:35:07-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0516f293-feff-426b-87da-0e18f83186c1' User entered '15 Mar 2021 23:35:07'	System	16 Mar 2021 03:35:10

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-03-24T19:34:22-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '36f20238-f48d-478b-9914-18ea77accabc'	System	24 Mar 2021 23:34:30
User entered 'No (N)'	System	24 Mar 2021 23:34:30

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-03-24T19:34:25-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '36f20238-f48d-478b-9914-18ea77accabc'	System	24 Mar 2021 23:34:30
User entered 'No (N)'	System	24 Mar 2021 23:34:30

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-03-24T19:34:28-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '36f20238-f48d-478b-9914-18ea77accabc'	System	24 Mar 2021 23:34:30
User entered '24 Mar 2021 19:34:28'	System	24 Mar 2021 23:34:30

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-03-30T09:25:04-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b9c54d5b-87b2-463d-92fb-504f4449142c'	System	30 Mar 2021 13:25:13
User entered 'No (N)'	System	30 Mar 2021 13:25:13

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-03-30T09:25:07-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b9c54d5b-87b2-463d-92fb-504f4449142c'	System	30 Mar 2021 13:25:13
User entered 'No (N)'	System	30 Mar 2021 13:25:13

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-03-30T09:25:10-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b9c54d5b-87b2-463d-92fb-504f4449142c' User entered '30 Mar 2021 09:25:10'	System	30 Mar 2021 13:25:13
	System	30 Mar 2021 13:25:13

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-04-05T06:04:42-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2ac94d21-52ba-4343-bebb-bcdb10353ca4'	System	05 Apr 2021 10:04:50
User entered 'No (N)'	System	05 Apr 2021 10:04:50

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-04-05T06:04:47-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2ac94d21-52ba-4343-bebb-bcdb10353ca4'	System	05 Apr 2021 10:04:50
User entered 'No (N)'	System	05 Apr 2021 10:04:50

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-04-05T06:04:50-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2ac94d21-52ba-4343-bebb-bcdb10353ca4'	System	05 Apr 2021 10:04:50
User entered '05 Apr 2021 06:04:50'	System	05 Apr 2021 10:04:50

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-04-12T18:12:32-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c37574de-4021-4c46-8f55-b5ea035e4329' User entered 'No (N)'	System	12 Apr 2021 22:14:11
	System	12 Apr 2021 22:14:11

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-04-12T18:12:35-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c37574de-4021-4c46-8f55-b5ea035e4329' User entered 'No (N)'	System	12 Apr 2021 22:14:11
	System	12 Apr 2021 22:14:11

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-04-12T18:12:37-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c37574de-4021-4c46-8f55-b5ea035e4329' User entered '12 Apr 2021 18:12:37'	System	12 Apr 2021 22:14:11
	System	12 Apr 2021 22:14:11

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-04-20T10:03:25-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '47c975bd-9e09-445f-97b8-676238f2740d' User entered 'No (N)'	System	20 Apr 2021 14:03:35
	System	20 Apr 2021 14:03:35

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-04-20T10:03:27-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '47c975bd-9e09-445f-97b8-676238f2740d'	System	20 Apr 2021 14:03:35
User entered 'No (N)'	System	20 Apr 2021 14:03:35

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-04-20T10:03:30-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '47c975bd-9e09-445f-97b8-676238f2740d' User entered '20 Apr 2021 10:03:30'	System	20 Apr 2021 14:03:35
	System	20 Apr 2021 14:03:35

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-04-25T00:28:39-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '174b2789-8fce-436e-98e0-8b148b16ac11' User entered 'No (N)'	System	25 Apr 2021 04:28:48
	System	25 Apr 2021 04:28:48

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-04-25T00:28:44-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '174b2789-8fce-436e-98e0-8b148b16ac11'	System	25 Apr 2021 04:28:48
User entered 'No (N)'	System	25 Apr 2021 04:28:48

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-04-25T00:28:46-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '174b2789-8fce-436e-98e0-8b148b16ac11'	System	25 Apr 2021 04:28:48
User entered '25 Apr 2021 00:28:46'	System	25 Apr 2021 04:28:48

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[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 (cee7959f773b7871)', Time: '2021-05-03T16:06:17-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '08f693e8-63fd-4b76-b407-5bd6d65bd579'	System	03 May 2021 20:06:25
User entered 'No (N)'	System	03 May 2021 20:06:25

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2021-05-03T16:06:19-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '08f693e8-63fd-4b76-b407-5bd6d65bd579'	System	03 May 2021 20:06:25
User entered 'No (N)'	System	03 May 2021 20:06:25

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-05-03T16:06:21-04:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '08f693e8-63fd-4b76-b407-5bd6d65bd579'	System	03 May 2021 20:06:25
User entered '03 May 2021 16:06:21'	System	03 May 2021 20:06:25

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:11:41

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-02-27T18:49:19-05:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cd199a49-d7f9-451a-8f91-8896af89c0f3'	System	27 Feb 2021 23:49:27
User entered 'No (N)'	System	27 Feb 2021 23:49:27

US3372060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:11:41

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2021-02-27T18:49:23-05:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cd199a49-d7f9-451a-8f91-8896af89c0f3' User entered '27 Feb 2021 18:49:23'	System	27 Feb 2021 23:49:27
	System	27 Feb 2021 23:49:27

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Nov 2020 15:20:24

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered '5 Nov 2020'	(b) (4) Danielle Theodore (b) (4)	05 Nov 2020 15:20:24

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	05 Nov 2020 15:20:24

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered empty.	(b) (4) Danielle Theodore (b) (4)	05 Nov 2020 15:20:24
	(b) (4)	

US3372060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:52
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Nov 2020 15:20:31

US3372060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:27
User entered 'I'	System	05 Nov 2020 15:20:31

US3372060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:51:51

US3372060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:51:51

US3372060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:51:51

US3372060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:51:51

US3372060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:51:57

US3372060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'I'	System	25 Jan 2021 19:51:57

US3372060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:52:26

US3372060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:52:26

US3372060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:52:26

US3372060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:52:26

US3372060

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:52:38

US3372060

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'I'	System	25 Jan 2021 19:52:38

US3372060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 09:11:09
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 22-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 09:11:06
User signature succeeded.	Mira Baron (b) (4)	22 Mar 2021 19:59:40
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Data updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 18:41:46
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 22-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:41:28

US3372060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 13:29:16
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 22-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:14:44
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	01 Feb 2021 17:06:09
	(b) (4)	

US3372060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	22 Mar 2021 19:59:40
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 08:50:51
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date correct as entered' (Site from System).	Danielle Theodore (b) (4) (b) (4)	01 Feb 2021 17:06:21
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Feb 2021 17:06:09
User entered '1 Feb 2021'	Danielle Theodore (b) (4) (b) (4)	01 Feb 2021 17:06:09

US3372060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	22 Mar 2021 19:59:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	01 Feb 2021 17:06:09
	(b) (4)	

US3372060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	22 Mar 2021 19:59:40
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	01 Feb 2021 17:06:09

US3372060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	01 Feb 2021 17:06:29
	(b) (4)	

US3372060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'I'	System	01 Feb 2021 17:06:29

US3372060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:26:57

US3372060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:26:57

US3372060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[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 11:29:07
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:26:57

US3372060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'VISIT4'	System	17 Mar 2021 14:26:57

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered '09:27'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered '16 Mar 2021 09:27'	System	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered '90'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'bpm'	System	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered '12'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'breaths/min'	System	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered '116'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'mmHg'	System	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:07:50
User entered '78'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'mmHg'	System	30 Mar 2021 19:23:27

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07

US3372060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07

US3372060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:27:03

US3372060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:27:03

US3372060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:27:30

US3372060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:27:30

US3372060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 15:55:40
User closed query ' Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" Collection Time is recorded here as 09:36 but in OL-D57 it is recorded as 09:58. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:59:10
Query ' Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" Collection Time is recorded here as 09:36 but in OL-D57 it is recorded as 09:58. Please clarify why there is a difference or update the field. Thank you!' answered with 'data corrected 09:58 is accurate per source' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 16:55:04
User entered '09:58' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 16:54:33
User opened query ' Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" Collection Time is recorded here as 09:36 but in OL-D57 it is recorded as 09:58. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 14:48:39
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '09:36'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:27:30

US3372060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered '16 Mar 2021 09:58'	System	31 Mar 2021 16:54:33
User entered '16 Mar 2021 09:36'	System	17 Mar 2021 14:27:30

US3372060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:27:33

US3372060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:29:07
User entered 'I'	System	17 Mar 2021 14:27:33

US3372060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:20
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:21
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Apr 2021 14:19:23

US3372060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:20
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:21
User entered '8 Apr 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Apr 2021 14:19:23

US3372060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:20
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Apr 2021 14:19:23

US3372060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:20
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:21
User entered empty.	(b) (4)	08 Apr 2021 14:19:23
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372060

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:20
User signature succeeded.	Mira Baron (b) (4)	08 Apr 2021 16:44:21
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Apr 2021 14:19:29

US3372060

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:20
User entered 'I'	System	08 Apr 2021 14:19:29

US3372060

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:42:21

US3372060

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22 Jan 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:42:21

US3372060

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Clinic (Clinic)'	Peter Jacob (b) (4)	23 Feb 2021 17:42:21

US3372060

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'UNBLND_DECIDE'	System	23 Feb 2021 17:42:21

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22 Jan 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:45:27

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:26:01
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:50:12

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:45:27

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:26:01
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:50:12

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22 Jan 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:45:27

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Placebo (Placebo)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:45:27

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Placebo (Placebo)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:45:27

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Placebo (Placebo)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:45:27

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:45:27

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '1'	System	23 Feb 2021 17:45:27

US3372060

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'I'	System	23 Feb 2021 17:45:27

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered missing code ND - Not Done.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered missing code ND - Not Done.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered empty.	System	23 Feb 2021 17:47:41
DataPoint set to visible.	System	23 Feb 2021 17:45:27

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered missing code ND - Not Done.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered missing code ND - Not Done.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered empty.	System	23 Feb 2021 17:47:41
DataPoint set to visible.	System	23 Feb 2021 17:45:27

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22 Jan 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '14:06'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '22 Jan 2021 14:06'	System	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '36.2' C	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Other (Other)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'forehead'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '84'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'bpm'	System	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '17'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'breaths/min'	System	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '140'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '89'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered missing code ND - Not Done.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered missing code ND - Not Done.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:47:41

US3372060

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered empty.	System	23 Feb 2021 17:47:41
DataPoint set to visible.	System	23 Feb 2021 17:45:27

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22 Jan 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '16:00'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '22 Jan 2021 16:00'	System	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '36.3' C	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Other (Other)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'forehead'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '99'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'bpm'	System	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'breaths/min'	System	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '142'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '90'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:17

US3372060

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	23 Feb 2021 17:48:17

US3372060

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:48:29

US3372060

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:48:29

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:09

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:49:09

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	Peter Jacob (b) (4)	23 Feb 2021 17:49:09

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mRNA-1273'	System	23 Feb 2021 17:49:09
DataPoint set to visible.	System	23 Feb 2021 17:45:27

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22 Jan 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:09

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '15:30'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:09

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '22 Jan 2021 15:30'	System	23 Feb 2021 17:49:09

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:09

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'ONCE'	System	23 Feb 2021 17:49:09

US3372060

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 17:49:09

US3372060

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:46:32

US3372060

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22 Jan 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:46:32

US3372060

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '14:17'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:46:32

US3372060

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '22 Jan 2021 14:17'	System	23 Feb 2021 17:46:32

US3372060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:46:44

US3372060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22 Jan 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:46:44

US3372060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:41

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '14:16'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:46:44

US3372060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:41

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '22 Jan 2021 14:16'	System	23 Feb 2021 17:46:44

US3372060

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

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:46:48

US3372060

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

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'I'	System	23 Feb 2021 17:46:48

US3372060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:33

US3372060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	Peter Jacob (b) (4)	23 Feb 2021 17:49:33

US3372060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:33

US3372060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	Peter Jacob (b) (4)	23 Feb 2021 17:49:33

US3372060

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:17

US3372060

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'I'	System	23 Feb 2021 17:49:17

US3372060

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'I'	System	23 Feb 2021 17:49:17
DataPoint set to visible.	System	23 Feb 2021 17:49:17

US3372060

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:46

US3372060

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '16 Feb 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:49:46

US3372060

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Clinic (Clinic)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:49:46

US3372060

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'OLD29'	System	23 Feb 2021 17:49:46

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4)	23 Feb 2021 17:50:18
	(b) (4)	

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '16 Feb 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '13:16'	Peter Jacob (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '16 Feb 2021 13:16'	System	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '36.5' C	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Other (Other)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'forehead'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '100'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'bpm'	System	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'breaths/min'	System	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '110'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '74'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	23 Feb 2021 17:50:18

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '16 Feb 2021'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '14:00'	Peter Jacob (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '16 Feb 2021 14:00'	System	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '36.5' C	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Other (Other)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'forehead'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '95'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'bpm'	System	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'breaths/min'	System	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '127'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '83'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	23 Feb 2021 17:50:54

US3372060

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:51:06

US3372060

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	Peter Jacob (b) (4)	23 Feb 2021 17:51:06

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mRNA-1273'	System	23 Feb 2021 17:51:50
DataPoint set to visible.	System	23 Feb 2021 17:49:17

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '16 Feb 2021'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '13:35'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '16 Feb 2021 13:35'	System	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'ONCE'	System	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 17:51:50

US3372060

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Feb 2021 17:51:54

US3372060

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'I'	System	23 Feb 2021 17:51:54

US3372060

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 18:43:25

US3372060

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '23 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 18:43:25
	(b) (4)	

US3372060

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 18:43:25

US3372060

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	23 Feb 2021 18:43:25
	(b) (4)	

US3372060

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 18:43:31
	(b) (4)	

US3372060

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'I'	System	23 Feb 2021 18:43:31

US3372060

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:18:55

US3372060

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:18:55

US3372060

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:18:55

US3372060

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'OLD57'	System	16 Mar 2021 21:18:55

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User closed query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM). Query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:19:59
User opened query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:23:40
User opened query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 14:49:21
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '09:27'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '16 Mar 2021 09:27'	System	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '90'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'bpm'	System	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '12'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'breaths/min'	System	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '116'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '78'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered 'mmHg'	System	16 Mar 2021 21:20:14

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56

US3372060

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56

US3372060

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:18

US3372060

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:18

US3372060

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:29

US3372060

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:29

US3372060

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:48:43
User entered '09:58'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:20:29

US3372060

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:26:56
User entered '16 Mar 2021 09:58'	System	16 Mar 2021 21:20:29

US3372060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:11:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:52
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 18:57:17

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:29:30
User entered	System	05 Oct 2020 12:29:26
'USA-US056-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	05 Oct 2020 12:29:26

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Hip injury - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 05:09:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	03 Oct 2020 05:09:53
Data point term sent to Coder	System	02 Oct 2020 19:06:40
User entered 'Right hip trauma'	Elena Acosta (b) (4)	02 Oct 2020 19:06:38
	(b) (4)	

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:16:16
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User closed query 'Per sponsor review, SAE resulted in hospitalization. Please update field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 10:50:53
Query 'Per sponsor review, SAE resulted in hospitalization. Please update field accordingly.' answered with 'corrected' (Site from DM).	Mary Sergalis (b) (4)	22 Feb 2021 19:17:36
DataPoint Un-verified.	Mary Sergalis (b) (4)	22 Feb 2021 19:17:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	22 Feb 2021 19:17:12
User opened query 'Per sponsor review, SAE resulted in hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '14 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '16 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:16:41
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 18:52:17
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	18 Dec 2020 17:42:06
DataPoint Un-verified.	Mary Sergalis (b) (4)	18 Dec 2020 17:41:56
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Dec 2020 17:41:56
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:05:57
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elena Acosta (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:58:32
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'The subject has not reported in type of treatment prolonged or directly for this AE.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:41:20
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 13:56:14
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Oct 2020 19:08:37
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Oct 2020 19:06:38
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
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	02 Oct 2020 19:08:37
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	02 Oct 2020 19:08:37
User entered '1' reason for change: Data Entry Error	Elena Acosta (b) (4)	02 Oct 2020 19:08:37
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) System	02 Oct 2020 19:06:38
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '14 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '16 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Not Related (NOT RELATED)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:16:53
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:59:05
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'AE is not related to study procedure.' (Site from DM).	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:13:08
DataPoint Un-verified.	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:13:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:13:02
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:05:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:16:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User closed query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse	(b) (4) (b) (4), (b) (6)	23 Feb 2021 10:51:00

Event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate.

' (Site from DM).

Query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse

Event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate.

' answered with 'updated' (Site from DM).

DataPoint Un-verified.

Mary Sergalis (b) (4) 22 Feb 2021 19:17:12

User entered 'None (NONE)' reason for change: Data Entry Error

Mary Sergalis (b) (4) 22 Feb 2021 19:17:12

User opened query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" only when adverse

(b) (4), (b) (6) 24 Dec 2020 03:20:02

Event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate.

' (Site from DM).

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:08
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Un-verified.	(b) (4)	
	Mary Sergalis (b) (4)	22 Feb 2021 19:17:12
User entered '1' reason for change: Data Entry Error	Mary Sergalis (b) (4)	22 Feb 2021 19:17:12
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:26:04
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.	(b) (4), (b) (6)	09 Nov 2020 14:43:33
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.	Mary Sergalis (b) (4)	06 Nov 2020 16:49:28
' answered with 'updated' (Site from DM).		
User entered '0' reason for change: Data Entry Error	Mary Sergalis (b) (4)	06 Nov 2020 16:49:05
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:33:43
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.	(b) (4), (b) (6)	30 Oct 2020 09:44:27
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '1'	Elena Acosta (b) (4)	02 Oct 2020 19:06:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:09
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 10:51:03
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	22 Feb 2021 19:17:54
DataPoint Un-verified.	Mary Sergalis (b) (4)	22 Feb 2021 19:17:12
User entered '0' reason for change: Data Entry Error	Mary Sergalis (b) (4)	22 Feb 2021 19:17:12
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:21:06
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:26:07
DataPoint Un-verified.	Mary Sergalis (b) (4)	06 Nov 2020 16:49:05
User entered '1' reason for change: Data Entry Error	Mary Sergalis (b) (4)	06 Nov 2020 16:49:05
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User closed query 'Per DM CLR: SAE Narrative = BICYCLE-MOTOR VEHICLE ACCIDENT. 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) (4), (b) (6)	23 Feb 2021 10:51:43
Query 'Per DM CLR: SAE Narrative = BICYCLE-MOTOR VEHICLE ACCIDENT. 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 'Not separate AE. subject was hit by a car.' (Site from DM).	Mary Sergalis (b) (4)	22 Feb 2021 19:18:18
User opened query 'Per DM CLR: SAE Narrative = BICYCLE-MOTOR VEHICLE ACCIDENT. 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)	11 Jan 2021 06:20:50
User closed query 'PV Query: Please provide results for CAT scan of the abdomen, CAT scan of the cervical spine, and x-ray of right knee (all on 14 Aug 2020).' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:51:29
User closed query 'PV Query: Please confirm the start date for CYCLOBENZAPRINE as it was after right knee injury was considered resolved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:51:18
Query 'PV Query: Please provide results for CAT scan of the abdomen, CAT scan of the cervical spine, and x-ray of right knee (all on 14 Aug 2020).' answered with 'CAT scan abdomen: No evidence of acute traumatic injury., CAT scan cervical spine: Normal with no acute traumatic injuries, Right Knee x-ray: No evidence of acute osseous injury' (Site from Safety).	Mary Sergalis (b) (4)	09 Nov 2020 15:40:19
Query 'PV Query: Please confirm the start date for CYCLOBENZAPRINE as it was after right knee injury was considered resolved.' answered with 'AE /concomitant medication updated ' (Site from Safety).	Mary Sergalis (b) (4)	09 Nov 2020 15:17:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results for CAT scan of the abdomen, CAT scan of the cervical spine, and x-ray of right knee (all on 14 Aug 2020).' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:03:37
User opened query 'PV Query: Please confirm the start date for CYCLOBENZAPRINE as it was after right knee injury was considered resolved.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:08:37
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Oct 2020 19:08:37
User entered 'After a bicycle-motor vehicle accident went to Delray Medical Center from 08/14/2020 to 08/16/2020 with Right Hip and Right Knee Trauma' reason for change: Data Entry Error	Elena Acosta (b) (4)	02 Oct 2020 19:08:37
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:06:38
User entered empty.	Elena Acosta (b) (4)	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 19:17:12
User entered '0'	System	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 19:06:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:29:55
User entered	(b) (4), (b) (6)	05 Oct 2020 12:29:51
'USA-US056-2020-mRNA-1273-P301000004'		

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:43:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Knee injury - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 05:09:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	03 Oct 2020 05:09:53
Data point term sent to Coder	System	02 Oct 2020 19:13:52
User entered 'Right knee trauma'	Elena Acosta (b) (4)	02 Oct 2020 19:13:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:40
User closed query 'Per sponsor review, SAE resulted in hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 05:55:54
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
Query 'Per sponsor review, SAE resulted in hospitalization. Please update field accordingly.' answered with 'data updated' (Site from DM).	(b) (4) Peter Jacob (b) (4)	22 Feb 2021 18:53:26
DataPoint Un-verified.	Peter Jacob (b) (4)	22 Feb 2021 18:53:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	22 Feb 2021 18:53:05
User opened query 'Per sponsor review, SAE resulted in hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:54:31
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:00
User entered 'No (N)'	Elena Acosta (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:44:03
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:44:07
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:44:10
User entered '14 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:44:12
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:12
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:14
User entered '04 Sep 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:16
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event, Right knee trauma, to grade 4.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:11
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event, Right knee trauma, to grade 4.' answered with 'data updated' (Site from Safety).	Peter Jacob (b) (4) (b) (4)	22 Feb 2021 18:53:33
DataPoint Un-verified.	Peter Jacob (b) (4) (b) (4)	22 Feb 2021 18:53:16
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	22 Feb 2021 18:53:16
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event, Right knee trauma, to grade 4.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:27
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:30
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:32
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:34
User entered 'I'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:37
User entered '14 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:39
User closed query 'PV Query: Please confirm hospital discharge date for the event of right knee trauma. Per the narrative, the subject was discharged from the hospital on 16 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:03:12
Query 'PV Query: Please confirm hospital discharge date for the event of right knee trauma. Per the narrative, the subject was discharged from the hospital on 16 Aug 2020.' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 14:41:29
User entered '16 Aug 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 14:41:14
User opened query 'PV Query: Please confirm hospital discharge date for the event of right knee trauma. Per the narrative, the subject was discharged from the hospital on 16 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:51:37
User entered '4 Sep 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:43
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:27
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:19
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:21
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:23
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:24
User entered 'Not Related (NOT RELATED)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:18
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:16
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:07
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:10
User entered 'I'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:03
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:46:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:45:59
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User closed query 'PV Query: Please confirm concomitant medications "Oxycontin" with indications of lower back pain and bilateral knee pain are separate entries and not duplicate dosing regimens.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:25
User closed query 'PV Query: Please confirm concomitant medications "Trazadone" and "Trazodone" with indications of lower back pain and bilateral knee pain are separate entries and not duplicate dosing regimens.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:52:21
Query 'PV Query: Please confirm concomitant medications "Oxycontin" with indications of lower back pain and bilateral knee pain are separate entries and not duplicate dosing regimens.' answered with 'separate entries' (Site from Safety).	Mary Sergalis (b) (4)	22 Feb 2021 19:21:04
Query 'PV Query: Please confirm concomitant medications "Trazadone" and "Trazodone" with indications of lower back pain and bilateral knee pain are separate entries and not duplicate dosing regimens.' answered with 'separate entries' (Site from Safety).	Mary Sergalis (b) (4)	22 Feb 2021 19:18:53
User opened query 'PV Query: Please confirm concomitant medications "Oxycontin" with indications of lower back pain and bilateral knee pain are separate entries and not duplicate dosing regimens.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 21:10:51
User opened query 'PV Query: Please confirm concomitant medications "Trazadone" and "Trazodone" with indications of lower back pain and bilateral knee pain are separate entries and not duplicate dosing regimens.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 21:08:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:58
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:03:19

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'No relevant laboratory. Diagnostic Test added' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 17:32:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:51:48
User entered 'After a bicycle-motor vehicle accident went to Delray Medical Center from 08/14/2020 to 08/16/2020 with Right Hip and Right Knee Trauma'	Elena Acosta (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 18:53:05
User entered '0'	System	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 19:13:05

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:47:07
User closed query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:14:40
Query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:03:25
User opened query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 09:49:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 22:26:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 22:26:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 22:26:39
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 22:26:36
User entered empty.	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 22:26:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:07:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:07:34
Data point term sent to Coder	System	26 Aug 2020 19:00:09
User entered 'ambien'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:07:10
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:47
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:16:53
User entered 'insomnia'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '10'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	26 Aug 2020 18:59:24
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 18:59:24
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 18:59:24
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	26 Aug 2020 18:59:24
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	26 Aug 2020 18:59:24
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Oct 2020 01:18:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:18:15
Data point term sent to Coder	System	06 Oct 2020 16:58:00
Coding entries removed.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:57:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:52:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:52:29
Data point term sent to Coder	System	26 Aug 2020 19:00:12
User entered 'trazodone'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 10:56:04
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:57:09
User entered 'bilateral knee pain' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:57:06
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:17:18
User entered 'pain knees neck lower back'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '100'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:00:06
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	26 Aug 2020 19:00:06
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:00:06
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:00:06
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:00:06
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:59:20
Data point term sent to Coder	System	06 Oct 2020 16:58:00
Coding entries removed.	Peter Jacob (b) (4)	06 Oct 2020 16:57:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:40
Data point term sent to Coder	System	26 Aug 2020 19:01:14
User entered 'oxycontin'	Peter Jacob (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	26 Aug 2020 19:00:29
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'bilateral knee pain' reason for change:	(b) (4)	
Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:57:26
User entered 'pain knees neck lower back'	(b) (4)	
	Peter Jacob (b) (4)	26 Aug 2020 19:00:29
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '15'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	26 Aug 2020 19:00:29
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:00:29
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'un UNK 2018'	Peter Jacob (b) (4)	26 Aug 2020 19:00:29
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	26 Aug 2020 19:00:29
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	26 Aug 2020 19:00:29
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 16:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:59:20
Data point term sent to Coder Coding entries removed.	System Peter Jacob (b) (4)	06 Oct 2020 16:58:01 06 Oct 2020 16:57:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:40
Data point term sent to Coder User entered 'aspirin'	System Peter Jacob (b) (4)	26 Aug 2020 19:01:16 26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 10:56:21
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:57:45
User entered 'cardiac prophylaxis' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:57:41
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:17:46
User entered 'prophylactic'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '81'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:00
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	26 Aug 2020 19:01:00
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:00
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
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)	27 Aug 2020 18:07:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:47
Data point term sent to Coder	System	26 Aug 2020 19:02:18
User entered 'influenza vaccine'	Peter Jacob (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0.25'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'un Sep 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'un Sep 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User entered empty.	System	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User entered empty.	System	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:01
User entered empty.	System	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Oct 2020 01:18:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:18:15
Data point term sent to Coder	System	06 Oct 2020 16:59:02
User entered 'trazadone'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'lower back pain'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '100'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'as needed (PRN)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Peter Jacob (b) (4)	26 Aug 2020 19:02:17
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:00:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 17:00:22
Data point term sent to Coder	System	06 Oct 2020 16:59:03
Coding entries removed.	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
Coding entries removed.	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:48
User entered 'oxycontin' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:56:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	02 Oct 2020 19:56:49
Data point term sent to Coder	System	02 Oct 2020 19:15:55
User entered 'Doxycycline'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
	(b) (4)	
User entered 'Yes (Y)'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'lower back pain' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	06 Oct 2020 16:58:48
User entered 'Right Knee Trauma laceration Infection Prevention'	(b) (4) Elena Acosta (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered '15' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
	(b) (4)	
User entered '100'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'mg (mg)'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty.	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'once daily (QD)' reason for change:	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
Data Entry Error	(b) (4)	
User entered 'twice daily (BID)'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty.	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'Oral (ORAL)'	(b) (4) Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty.	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'un UNK 2018' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
	(b) (4)	
User entered '16 Aug 2020'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered '0'	(b) (4) Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
	(b) (4)	
User entered 'No (N)'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
	(b) (4)	
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
	(b) (4)	
User entered '26 Aug 2020'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User entered 'No (N)'	(b) (4) Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:58:48
User entered '2'	System	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:03:24
User closed query 'Please verify if the following medications noted in the hospital records should be added: pancrelipase, oxycodone, doxycycline IV, zolpidem and senna.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:03:22
Query 'Please verify if the following medications noted in the hospital records should be added: pancrelipase, oxycodone, doxycycline IV, zolpidem and senna.' answered with 'ANTIBIOTIC. TAKING ONLY FOR DAYS AS RECORDED.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 13:47:24
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:18
User opened query 'Please verify if the following medications noted in the hospital records should be added: pancrelipase, oxycodone, doxycycline IV, zolpidem and senna.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:28:14
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:01:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:01:15
Data point term sent to Coder	System	06 Oct 2020 17:00:05
User entered 'doxycycline'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:32
User entered 'right knee trauma laceration infection prevention'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:34
User entered '100'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:37
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:38
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:45
User entered 'twice daily (BID)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:43
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:41
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:50
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:48
User entered '16 Aug 2020'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:20:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:59
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:57
User entered '26 Aug 2020'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:19:53
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User entered '2'	System	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User entered '1'	System	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:08
User entered '804 (804)'	System	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 03:30:52
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 03:30:52
Data point term sent to Coder	System	09 Nov 2020 15:16:53
Coding entries removed.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:07
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:37:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 22:33:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 22:33:33
Data point term sent to Coder	System	19 Oct 2020 17:32:24
User entered 'Cyclobenzaprine'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:27
User entered 'No (N)'	Mary Sergalis (b) (4) (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:30
User closed query 'Per CDM: Indication of this Medication is "Right Knee Trauma" and has a start date of "17Oct2020", however the AE for Right Knee Truma has an end date of 04Sep2020. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:06:50
User entered 'RIGHT KNEE Pain' reason for change: Data Entry Error	Mary Sergalis (b) (4)	09 Nov 2020 15:16:07
Query 'Per CDM: Indication of this Medication is "Right Knee Trauma" and has a start date of "17Oct2020", however the AE for Right Knee Truma has an end date of 04Sep2020. Please review and clarify or update accordingly. ' answered with 'RIGHT KNEE TRAUMA HAS START DATE OF 14 AUG 2020, WITH THE END DATE OF 04 SEPT 2020 AS RECORDED.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:51:05
User opened query 'Per CDM: Indication of this Medication is "Right Knee Trauma" and has a start date of "17Oct2020", however the AE for Right Knee Truma has an end date of 04Sep2020. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:40:10
User entered 'Right Knee Trauma'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:31
User entered '10'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:33
User entered 'mg (mg)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:35
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:37
User entered 'once daily (QD)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:42
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:44
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:47
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:07:51
User closed query 'Please verify, noted in esource as 17Aug2020 and continuing.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:07:32
Query 'Please verify, noted in esource as 17Aug2020 and continuing.' answered with 'updated' (Site from CRA).	Mary Sergalis (b) (4)	10 Nov 2020 15:39:19
User entered '17 Aug 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 15:39:03
User opened query 'Please verify, noted in esource as 17Aug2020 and continuing.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 21:30:02
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:51:18
User entered '17 Oct 2020'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:10:27
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:51:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 20:48:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:51:18
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:51:19
User closed query 'Please verify, noted in source as continuing.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:51:16
Query 'Please verify, noted in source as continuing.' answered with 'corrected' (Site from CRA).	Mary Sergalis (b) (4)	10 Nov 2020 20:48:51
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 20:48:41
User opened query 'Please verify, noted in source as continuing.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:08:11
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:51:18
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:10:07
User entered 'No (N)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DIGESTIVES, INCL. ENZYMES, ATC: DIGESTIVES, INCL. ENZYMES, ATC: ENZYME PREPARATIONS, PRODUCT: PANCRELIPASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:04:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:04:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:35
Data point term sent to Coder	System	10 Nov 2020 17:16:30
User entered 'Pancrelipase'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:51:38
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:06:45
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 19:36:46
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 03:42:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:41
User entered 'Pancreatic Enzyme Replacement'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:51:43
User entered '36000'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:51:46
User entered 'IU (IU)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:51:51
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:51:54
User entered 'twice daily (BID)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:51:57
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:00
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:02
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:10
User entered '15 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:08
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:14
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:15
User entered '16 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:17
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User entered '2'	System	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User entered '1'	System	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:13
User entered '804 (804)'	System	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 15:14:34
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 15:14:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:55
Data point term sent to Coder	System	10 Nov 2020 17:17:31
User entered 'Morphine'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:57
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:52:59
User entered 'Right Knee Pain'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:01
User entered '2'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:04
User entered 'mg (mg)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:06
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:07
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:09
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:12
User entered 'Intravenous (INTRAVENOUS)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:13
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:16
User entered '15 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:18
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:20
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:22
User entered '15 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:53:24
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User entered empty.	System	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User entered empty.	System	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:20
User entered empty.	System	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 15:17:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	11 Nov 2020 15:17:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:08
Data point term sent to Coder	System	10 Nov 2020 17:19:44
User entered 'Percocet 5/325'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:10
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:16
User entered 'Right Knee Pain'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:19
User entered 'I'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:22
User entered 'tablet (TABLET)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:23
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:25
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:27
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:29
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:32
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:34
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:35
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:38
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:46
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:55:48
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User entered empty.	System	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User entered empty.	System	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:26
User entered empty.	System	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:17:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:17:47
Data point term sent to Coder	System	10 Nov 2020 17:21:46
User entered 'Cefazolin'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:08
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:10
User entered 'Right Knee Laceration'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:13
User entered 'l'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:16
User entered 'g (g)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:17
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	(b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:19
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:21
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:24
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:25
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:27
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:29
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:51
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:53
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:56:56
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User entered empty.	System	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User entered empty.	System	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:32
User entered empty.	System	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
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)	10 Nov 2020 23:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 23:54:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:31
Data point term sent to Coder	System	10 Nov 2020 17:23:49
User entered 'Iopamidol'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:32
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:34
User entered 'Radiopaque Contrast Agent'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:35
User entered 'I'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:40
User entered 'mL (mL)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:44
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:43
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:46
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:47
User entered 'Intravenous (INTRAVENOUS)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:49
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:52
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:54
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:56
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:01:59
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:00
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User entered empty.	System	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User entered empty.	System	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:36
User entered empty.	System	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User closed query 'Per CDM-MM requery: Response Noted, However please ensure a protocol deviation is captured. If correct.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:29:04
Query 'Per CDM-MM requery: Response Noted, However please ensure a protocol deviation is captured. If correct.' answered with 'done' (Site from DM).	Peter Jacob (b) (4) (b) (4)	09 Dec 2020 16:42:27
User opened query 'Per CDM-MM requery: Response Noted, However please ensure a protocol deviation is captured. If correct.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 06:54:05
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 06:54:05
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' answered with 'data correct as is' (Site from DM).	Mary Sergalis (b) (4)	07 Dec 2020 18:16:19
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:36:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 01:57:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	11 Nov 2020 01:57:45 10 Nov 2020 21:02:32
Data point term sent to Coder	System	10 Nov 2020 17:24:50
User entered 'Adacel (Tdap)'	Mary Sergalis (b) (4) (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 09:02:45
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	02 Feb 2021 17:57:28
DataPoint Un-verified.	Mary Sergalis (b) (4)	02 Feb 2021 17:57:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	02 Feb 2021 17:57:19
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 03:43:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:34
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:35
User entered 'Tetanus Prophylaxis/Prevention'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:37
User entered '0.5'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:38
User entered 'mL (mL)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:40
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:41
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:46
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:44
User entered 'Intramuscular (INTRAMUSCULAR)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:47
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:49
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:50
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:54
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:53
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:57
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User entered empty.	System	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User entered empty.	System	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:01
User entered empty.	System	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:11:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:07
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 17:20:25
User entered 'No (N)'	Peter Jacob (b) (4)	11 Aug 2020 22:26:44

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:41

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 17:21:10

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'CAT Scan of the Abdomen'	Mary Sergalis (b) (4)	19 Oct 2020 17:21:10

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	19 Oct 2020 17:21:10

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:41

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:21:10

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:41

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 17:22:58

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'CAT Scan of the Cervical Spine'	Mary Sergalis (b) (4)	19 Oct 2020 17:22:58

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	19 Oct 2020 17:22:58

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:22:58

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:10
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 17:28:13

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:10
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'X-Ray of Right Knee'	Mary Sergalis (b) (4)	19 Oct 2020 17:28:13

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:10
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	19 Oct 2020 17:28:13

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:10
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:28:13

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 19:53:09
User entered '7'	System	22 Feb 2021 19:53:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
	(b) (4)	
User entered '6'	System	21 Dec 2020 18:52:49
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 19:53:09
User entered '7'	System	22 Feb 2021 19:53:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
	(b) (4)	
User entered '6'	System	21 Dec 2020 18:52:49
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:11:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:21
User entered '05/Oct/2020 08:32'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:11:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered '1' reason for change: New Information	(b) (4), (b) (6)	05 Oct 2020 12:32:06
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 12:31:57

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 19:53:09
User entered '7'	System	22 Feb 2021 19:53:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
	(b) (4)	
User entered '6'	System	21 Dec 2020 18:52:49
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:11:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:33:24
User entered '20/Oct/2020 14:03'	System	20 Oct 2020 14:03:40

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:11:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:52:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:25
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 14:03:40

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 19:53:09
User entered '7'	System	22 Feb 2021 19:53:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
	(b) (4)	
User entered '6'	System	21 Dec 2020 18:52:49
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:11:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered '09/Nov/2020 20:53'	(b) (4) System	09 Nov 2020 20:53:10

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:11:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 17:55:18
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 20:53:10

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 19:53:09
User entered '7'	System	22 Feb 2021 19:53:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
	(b) (4)	
User entered '6'	System	21 Dec 2020 18:52:49
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:11:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered '19/Nov/2020 17:55'	(b) (4) System	19 Nov 2020 17:55:37

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:11:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:03:59
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 17:55:37

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 19:53:09
User entered '7'	System	22 Feb 2021 19:53:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
	(b) (4)	
User entered '6'	System	21 Dec 2020 18:52:49
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:11:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:44:39
User entered '19/Nov/2020 18:04'	System	19 Nov 2020 18:04:12

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:11:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:52:52
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:44:41
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 18:04:12

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 19:53:09
User entered '7'	System	22 Feb 2021 19:53:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
	(b) (4)	
User entered '6'	System	21 Dec 2020 18:52:49
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:11:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
User entered '21/Dec/2020 13:52'	(b) (4) System	21 Dec 2020 18:52:49

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:11:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:52:57
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 18:52:49

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

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Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

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Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 19:53:09
User entered '7'	System	22 Feb 2021 19:53:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 16:26:11
	(b) (4)	
User entered '6'	System	21 Dec 2020 18:52:49
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:11:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:11
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered '22/Feb/2021 13:53'	(b) (4) System	22 Feb 2021 19:53:09

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:11
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:46:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:53:09